

1. Product and Company Identification

1.1	Product name	Glucose and Bilirubin Calibrator
	Substance/mixture	Mixture
	CAS #	Mixture
	Kit number	MD-101213
1.2	Recommended product use	
	Mixture's intended use	Diagnostic reagent for IN VITRO quantitative measurement of glucose and total bilirubin 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., Meredith, 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

2.1	Substance or mixture classification	
	Physical state	Lyophilized – Liquid after reconstitution
	Appearance	light yellow; clear
	Emergency overview	Health injuries are not known or expected under normal use.
2.2	Label Elements	
	Signal word	None
	Hazardous substances	This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.
	OSHA regulatory status	This product is not hazardous according to OSHA 29CFR 1910.1200.

3. Composition/Information on ingredients

Hazardous Ingredients: None

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	If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.
Ingestion	If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.
Notes to Physician	Provide general supportive measures and treat symptomatically.
General Advice	If you feel unwell, seek medical advice.

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 (CO ₂), 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	No combustion products posing significant hazards are expected from this product

6. Accidental Release Measures

6.1 Personal precautions	This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.
6.2 Environmental precautions	Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water
6.3 Methods for containment and cleaning up	If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations. If the product is in solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.

6.4 Other information

Clean up in accordance with all applicable regulations.

7. Handling and Storage

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|-----------------------------|---|
| 7.1 Safe Handling | This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product. |
| 7.2 Hygiene Measures | Wash exposed skin thoroughly after handling |
| 7.2 Storage | Store at 2-8°C as directed on product label. To maintain product quality, store according to the instructions in the product labeling. Store away from strong acids, strong bases, strong oxidizers and incompatible materials. |
| 7.3 Specific use | See section 1 – Recommended Use |

8. Exposure Controls / Personnel

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| 8.1 Occupational exposure limits | No exposure limits noted for ingredient(s). |
| Exposure guidelines | Follow standard monitoring procedures. |
| Engineering controls | No special engineering controls are required. Use with good general ventilation. |
| 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

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| 9.1 Information on basic physical and chemical properties | |
| Physical state | Lyophilized, Liquid after reconstitution |
| Color | Light Yellow |
| Odor | Slight odor |
| Odor threshold | No data available |
| pH | 7.0 – 8.5 |
| 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) | 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 To maintain product performance keep away from strong acids, strong bases, strong oxidizers. A void exposure to heat and direct sunlight.

10.5 Incompatible materials No data available

10.6 Hazardous polymerization No data available

10.7 Hazardous decomposition Products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

11. Toxicological Information

11.1 Information on toxicological effects

Sensitization Not classified.

Acute effects No data available

Local effects No data available

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

Common routes of entry include inhalation, ingestion and eye/skin contact.

Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material..

Additional information This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

12. Ecological Information

12.1 Toxicity

Ecotoxicity No data available

Environmental effects No data available

12.2 Persistence and degradability

No data is available on the degradability of this product.

12.3 Bioaccumulation/Accumulation

No data available

12.4 Mobility in environmental media

No data available

13. Disposal Considerations

13.1 Disposal methods

Disposal instructions

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

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).

Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.

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.