

1. Product and Company Identification

1.1	Product name	Urobilinogen Calibrator
	Substance/mixture	Mixture
	CAS #	Mixture
	Kit number	MD-101203.01, MD-101203.02
1.2	Recommended product use	
	Mixture's intended use	Diagnostic reagent for IN VITRO quantitative measurement of urobilinogen 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

Classification Skin Irritant, Eye Irritant



2.1 Substance or mixture classification

Physical state	Lyophilized – Liquid after reconstitution
Appearance	Golden Yellow; clear
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.

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

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

Components:

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Urobilinogen	14684-37-8	Classification not possible based on information available.	<100%*

*Exact concentration withheld as it is considered a 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

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 rinses 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 (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	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	Use standard firefighting procedures and consider the hazards of other involved materials. Avoid contaminating surface water with fire extinguishing water.
Hazardous combustion Products	Hazardous combustion gases or vapors may develop 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. Ensure adequate ventilation.
6.2 Environmental precautions	Do not allow 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 -27°C to -6°C (-16.6°F to 21.2°F). 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
Urobilinogen 14684-37-8	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**
- Physical state** Lyophilized, Liquid after reconstitution
- Color** Golden Yellow Solution
- Odor** Odorless
- Odor threshold** No data available
- pH** 10.0 – 12.0 @ 25°C
- 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	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 Conditions to avoid	No data available
10.5 Incompatible materials	No data available
10.6 Hazardous polymerization	No data available
10.7 Hazardous decomposition Products	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

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.

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

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)

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.