

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: MicroVue Osteocalcin EIA kit (Catalog #: 8001, 8002)

Intended Use: The Osteocalcin immunoassay quantitatively measures intact (*de novo*) osteocalcin in serum or EDTA plasma. Intact osteocalcin may be useful as a biochemical indicator of bone turnover.

Cat. #8001: For **Research Use Only** in the United States. Not for use in diagnostic procedures.

Cat. #8002: For *In Vitro Diagnostic* use. For export only. Not for sale or use in the United States or Canada.



Components: Osteocalcin Standards A → F (lyophilized), Low Control, High Control, Coated Strips, Stop Solution, 10X Wash Buffer, Anti-Osteocalcin, Substrate Buffer, Substrate Tablets and Enzyme Conjugate.

Section 2 – Hazards Identification

Classification of Substance or Mixture

Component	OSHA Hazards	Target Organs	GHS Classification
Stop Solution (1.5% Sodium Hydroxide)	Irritant	Eyes and Skin	Skin Irritation (Category 2) Eye Irritation (Category 2)
Substrate Buffer (11.5% Diethanolamine)	Irritant	Eyes, Skin and Liver	Eye Irritation (Category 2B) Skin Irritation (Category 2) Specific Target Organ Toxicity (STOT RE2)

GHS Label Elements, Including Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
Stop Solution (1.5% Sodium Hydroxide)	 Warning	H315 Causes skin irritation. H319 Causes serious eye irritation.	P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Substrate Buffer (11.5% Diethanolamine)	 Warning	H302 Harmful if swallowed H315 Causes skin irritation. H319 Causes serious eye irritation. H373 May cause damage to the liver through prolonged or repeated exposure	P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Section 2 – Hazards Identification (cont'd)

Supplemental Hazard Statements

1. Follow Universal Precautions when working with this kit. Refer to additional Universal Precautions information in Section 7, Handling and Storage.
2. Avoid release to the environment.
3. Sodium azide is used as a preservative (<0.1%) in various components. Avoid disposal of this material down sanitary or industrial plumbing systems.

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Stop Solution (4702)	Sodium Hydroxide	1310-73-2	215-185-5	1.5	15 mL
Substrate Buffer (4705)	Diethanolamine	111-42-2	203-868-0	11.5	30 mL (3 x 10 mL)

Section 4 – First Aid Measures

General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

- If inhaled:* Move the person to fresh air and support breathing as required.
- In case of skin contact:* Wash affected area with soap and water. Seek medical advice if irritation develops.
- In case of eye contact:* Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.
- If swallowed:* Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops. **Stop Solution:** Do not induce vomiting.
- Note to Physicians:* Treat symptomatically.

Section 5 – Fire Fighting Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

- Extinguishing Media:* For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available.
- Fire Fighting Equipment:* Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
<i>Materials and Methods for Clean-Up:</i>	Wipe up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

Specific Use: Refer to product specific Package Insert.

Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

Conditions for Safe Storage: To maintain efficacy, store according to the kit specific Package Insert instructions.

Incompatibilities To maintain efficacy, store according to the kit specific Package Insert instructions.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the specific components within this kit.

Exposure Controls:

Engineering Measures Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection: None needed under normal conditions of use.

Hand Protection: Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

Eye Protection: Wear safety glasses with side shields or goggles to prevent eye contact.

Section 8 – Exposure Controls and Personal Protection (cont'd)

Skin and Body Protection: Use body protection appropriate for the task. A laboratory coat is recommended.

Hygiene Measures: Wash hands before and after use and at the end of the workday.

Environmental Exposure Controls

No special environmental controls are required.

Section 9 – Physical and Chemical Properties

Characteristic	Stop Solution (4702)	Substrate Buffer (4705)
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available
pH	<13	9.9
Solubility in Water	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Clear liquid, mild ammonia like odor

Section 10 – Stability and Reactivity

Characteristic	Stop Solution (4702)	Substrate Buffer (4705)
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	No data available	No data available
Materials to Avoid	No data available	No data available
Hazardous Decomposition Products	No data available	No data available

Section 11 – Toxicological Information

Acute Toxicity

Component Analysis – LD50 / LC50 / Irritation (No data available for specific kit components)

Chemical Name	CAS #	RTECS #	Information
Sodium Hydroxide	1310-73-2	WB490000	Oral LD ₅₀ No data available Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available
Diethanolamine	111-42-2	KL2975000	Oral LD ₅₀ Rat 1600 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ Rabbit <12,200 mg/kg

Potential Health Effects: Stop Solution (4702) and Substrate Buffer (4705) – Irritant

Skin Corrosion/ Irritation: No data available.

Inhalation: May cause respiratory tract irritation.

Serious Eye Damage / Irritation: No data available.

Skin: May cause skin irritation upon contact.

Respiratory or Skin Sensitization: No data available.

Eyes: May cause serious eye irritation.

Generative Cell Mutagenicity: No data available.

Ingestion: May be harmful if swallowed.

Carcinogenicity

Substrate Buffer IARC: 2B – Group 2B

Diethanolamine Possibly carcinogenic to humans.

Reproductive Toxicity

No data available.

Teratogenicity

No data available.

Specified Target Organ General Toxicity (GHS)

Single Exposure (GHS): No data available.

Repeated Exposure (GHS): No data available.

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components contained within this kit.

Synergistic Effects

No data available.

Additional Information

Substrate Buffer: Liver Irregularities – Based on human evidence. (Diethanolamine)

Section 12 – Ecological Information

Ecotoxicity

No data available.

Mobility in Soil

No data available.

Persistence / Degradability

No data available.

PBT and vPvB Assessment

No data available.

Bioaccumulation

No data available.

Other Adverse Effects

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

Section 13 – Disposal Considerations

Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)

This kit is not regulated for transport.

International Air Transportation (IATA)

This kit is not regulated for transport.

International Maritime Dangerous Goods (IMDG)

This kit is not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards Stop Solution (4702): Irritant
 Substrate Buffer (4705): Irritant

SARA 302 The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
 No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
 Diethanolamine CAS#: 111-42-2 Revision Date: 2011-07-01

SARA 311/312 Sodium Hydroxide CAS#: 1310-73-2 Acute Health Hazard
 Diethanolamine CAS#: 111-42-2 Acute Health Hazard, Chronic Health Hazard

State Regulations

The following chemicals appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Sodium Hydroxide	1310-73-2	Yes	Yes	Yes	Yes	Yes	Yes
Diethanolamine	111-42-2	Yes	Yes	Yes	Yes	Yes	Yes

California Prop 65: Substrate Buffer – **Warning!** – This kit contains a chemical known to the State of California to cause cancer.

Diethanolamine CAS#: 111-42-2 Revision Date: 2012-07-20

Section 15 – Regulatory Information (cont'd)

Canadian - WHMIS Classification (Raw Material)

Chemical Name	CAS #	Classification
Sodium Hydroxide	1310-73-2	E Corrosive - Corrosive to skin.
Diethanolamine	111-42-2	D2A Very Toxic Material Causing Other Toxic Effects Chronic toxicity D2B Toxic Material Causing Other Toxic Effects - Carcinogen - Moderate skin irritant - Severe eye irritant

Additional Regulatory Information
Safety, Health and Environmental regulations/legislation specific for the mixture:

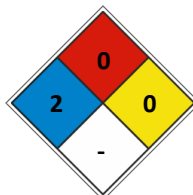
European Union – Regulation (EC) No. 1907/2006

Chemical Safety Assessment:

Not completed for the components contained within this kit.

NFPA Kit Classification:

Health Hazard (blue):	2
Fire Hazard (red):	0
Reactivity Hazard (yellow):	0
Special Hazards (white):	None



Section 16 – Other Information

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SUPERCEDES: June 8, 2017

REVISIONS: Section 15, added EU regulatory reference.

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.