

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: MicroVue 25-OH Vitamin D EIA kit (Catalog #: 8046)

Intended Use: An Enzyme Immunoassay (EIA) for the quantitative determination of 25-hydroxyvitamin D₂ and D₃ (25OH D₂ and 25OH D₃) in human serum. This kit is for *in vitro diagnostic* use.


Components: 25-OH Vitamin D Standard, 25-OH Vitamin D Standards B → F, 25-OH Control (Control 1), 25-OH Control (Control 2), Microassay Plate, Stop Solution, 20X Wash Buffer Concentrate, TMB Substrate, Biotinylated 25-OH Vitamin D, Concentrated HRP, Reconstitution Solution, and Assay Buffer.

Section 2 – Hazards Identification




Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Stop Solution (<4% Hydrochloric Acid)	Corrosive	Eyes and Skin	Skin Corrosive (Category 1B)
25-OH Standards, 25-OH Controls (1 and 2), Reconstitution Solution, Assay Buffer (<0.06% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
Assay Buffer (<1% PFOA)	Possible Carcinogen Irritant	Reproductive Skin	Skin Sensitizer (Category 1) Carcinogenicity (Category 2) Reproductive Toxicity (Category 1); Lact.

GHS Classification and Label Elements

Kit Component	Pictogram	Hazard Statements	Precautionary Statements
Stop Solution (<4% Hydrochloric Acid)	 Danger	H303 May be harmful if swallowed. H314 Causes severe skin burns and eye damage.	P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. P301+P330+P331: IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. 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)

Kit Component	Pictogram	Hazard Statements	Precautionary Statements
25-OH Standards, 25-OH Controls (1 and 2), Reconstitution Solution, Assay Buffer (<0.06% Proclin 300)	 Warning	H317 May cause an allergic skin reaction.	P264 Wash hands thoroughly after handling. P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P333+P313: If skin irritation or rash occurs: Get medical attention.
Assay Buffer (<1% PFOA)	  Danger	H317 May cause an allergic skin reaction H351 Suspected of causing cancer H360D May damage the unborn child. H362 May cause harm to breast-fed children H372 Causes damage to organs through prolonged or repeated exposure	P281 Use personal protective equipment as required P302+352 If ON SKIN: Wash with soap and water P308+313 If exposed or concerned: Get medical advice/attention P333+313 If skin irritation or a rash occurs: Get medical advice/attention
Supplemental Hazard Statements	<ol style="list-style-type: none"> Follow Universal Precautions when working with this kit. Refer to additional Universal Precautions information in Section 7, Handling and Storage. The Assay Buffer, Standards, Controls and Reconstitution Solution contain materials from animal origin. Avoid release to the environment. <u>Assay Buffer (PFOA)</u>: This mixture contains a component considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent or very bioaccumulative (vPvB). 		

Section 3 – Composition / Information on Ingredients

Kit Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Stop Solution	Hydrochloric Acid	7647-01-0	231-595-7	<4	12 mL
1. 25-OH Standards, 2. 25-OH Controls (1 and 2), 3. Reconstitution Solution, 4. Assay Buffer	Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	<0.06	1. ≤2 mL 2. 1 mL 3. 30 mL 4. 20 mL
Assay Buffer	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	206-397-9	<1	20 mL

*All the above listed components are mixtures.

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. Seek medical advice if irritation develops.
- 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.

- Personal Precautions:* 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.
- Materials and Methods for Clean-Up:* 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.
- Recovery and Neutralization:* Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
- Environmental Precautions:* Contain spill to prevent migration to public industrial / sanitary sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

Specific Use: For *In Vitro Diagnostic* use. Not for use by the general public.

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 (e.g., nitrile or equivalent). 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.

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 (<4% Hydrochloric Acid)	Assay Buffer (<1% PFOA; <0.06% Proclin 300)	Standards, Controls (<0.06% Proclin 300)
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available

Section 9 – Physical and Chemical Properties (cont'd)

Characteristic	Stop Solution (<4% Hydrochloric Acid)	Assay Buffer (<1% PFOA; <0.06% Proclin 300)	Standards, Controls (<0.06% Proclin 300)
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	<2	6.1 to 6.6	Neutral
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Clear liquid, odorless	Lyophilized solid, odorless

Section 10 – Stability and Reactivity

Characteristic	Stop Solution (<4% Hydrochloric Acid)	Assay Buffer (<1% PFOA; <0.06% Proclin 300)	Standards, Controls (<0.06% Proclin 300)
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	No data available	No data available	No data available
Conditions to Avoid	No data available	No data available	No data available
Materials to Avoid	No data available	No data available	No data available
Hazardous Decomposition Products	No data available	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
Hydrochloric Acid	7147-01-0	MW4025000	Oral LD ₅₀ Rabbit 900 mg/kg Inhalation LC ₅₀ Mouse 1108 PPM/1H Dermal LD ₅₀ No data available
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	Oral LD ₅₀ Rat 53 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	RH0781000	Oral LD ₅₀ No data available Inhalation LC ₅₀ No data available Intraperitoneal LD ₅₀ Rat 189 mg/kg

Potential Health Effects: Stop Solution, Assay Buffer, Standards and Controls

Skin Corrosion/Irritation:

Rabbit – Causes burns (Stop Solution)

Serious Eye Damage / Irritation:

Rabbit – corrosive to eyes (Stop Solution)

Respiratory or Skin Sensitization:

No data available

Generative Cell Mutagenicity:

Genotoxicity in vivo – rat – oral: DNA damage (Assay Buffer)

Genotoxicity in vivo – rat – intraperitoneal: DNA damage (Assay Buffer)

Section 11 – Toxicological Information (cont'd)

Symptoms of Exposure

<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Skin:</i>	May cause skin irritation upon contact.
<i>Eyes:</i>	May cause serious eye irritation.
<i>Ingestion:</i>	May be harmful if swallowed.

Carcinogenicity

IARC, Group 3:	Not classified as to its carcinogenicity to humans (Hydrochloric Acid)
IARC, Group 2B:	Possibly carcinogenic to humans (PFOA)

Reproductive Toxicity

Assay Buffer: Presumed human reproductive toxicant (PFOA)

Teratogenicity

Assay Buffer: Effects on or via lactation (PFOA)

Specified Target Organ General Toxicity (GHS)

<i>Single Exposure (GHS):</i>	<u>Stop Solution:</u> May cause respiratory tract irritation with a single exposure.
<i>Repeated Exposure (GHS):</i>	<u>Assay Buffer:</u> May cause damage to organs through prolonged or repeated exposure – Liver (PFOA)

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

<u>Stop Solution:</u>	Stomach – Irregularities – Based on Human Evidence (Hydrochloric Acid)
<u>Assay Buffer:</u>	Stomach – Irregularities – Based on Human Evidence (PFOA)
<u>Sensitization:</u>	Contains a small volume of a very dilute, sensitizing preservative (Proclin 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

Section 12 – Ecological Information

Ecotoxicity

No data available

Persistence / Degradability

No data available

Bioaccumulation

No data available

Mobility in Soil

No data available

PBT and vPvB Assessment

Assay Buffer: This mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

Other Adverse Effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

- *Proclin 300 is very toxic to aquatic life with long lasting effects*
- *PFOA is harmful to aquatic life.*

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 (A3673), 20X Wash Solution (A9957), Sample Diluent (A3670) and CIC-Raji Confirmation Diluent (A9511): 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:		
	Hydrochloric Acid	CAS#: 7647-01-0	Revision Date: 1993-04-24
SARA 311/312	Hydrochloric Acid	CAS#: 7647-01-0	Acute Health Hazard
	Proclin 300	CAS#: 55965-84-9	Acute Health Hazard
	PFOA	CAS#: 335-67-1	Acute Health Hazard, Chronic Health Hazard

State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Hydrochloric Acid	7647-01-0	Yes	Yes	Yes	Yes	Yes	No
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	No	No	No	Yes	Yes	No
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	No	No	No	Yes	Yes	No

California Prop 65: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Section 15 – Regulatory Information (cont'd)

Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
Hydrochloric Acid	6153-56-6	E Corrosive Material (skin)
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	No data available
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	D2A Very toxic material causing other toxic effects (teratogen, carcinogen, reproductive hazard)

Section 15 – Regulatory Information (cont'd)

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

Authorizations and/or restrictions on Use: PFOA CAS #: 335-67-1

REACH: Candidate List of Substances of Very High Concern for Authorization (Article 59) (PFOA)

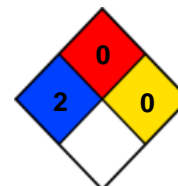
Toxic for reproduction (Article 57c) (PFOA)

Restricted for professional users.

Chemical Safety Assessment:

Not completed for the components contained within this kit.

HMIS Kit Classification:

NFPA Kit Classification:


Section 16 – Other Information

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