

Section 1 – Product and Company Identification

Manufacturer Information

Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701

Phone: 1.800.874.1517
Fax: 1.740.592.9820
Emergency #: 1.866.519.4752

Web: quidel.com
E-mail: gehs@quidel.com

Product Information

Product Name: High Sensitivity Human PTH (1-34) ELISA Kit (Catalog #: 60-3900)

Intended Use: This kit is intended for research use only in the determination of human PTH (1-34) levels in plasma or cell culture media.

Components: Streptavidin Coated Microtiter Plate, High Sensitivity Human PTH (1-34) Biotinylated Antibody, High Sensitivity Human PTH (1-34) HRP Antibody, High Sensitivity Human PTH (1-34) Standards, High Sensitivity Human PTH (1-34) Controls I & II, ELISA Wash Concentrate, ELISA HRP Substrate, ELISA Stop Solution, and Plate Sealer.


Section 2 – Hazards Identification

Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
ELISA Stop Solution (5.65% Sulfuric Acid)	Corrosive	Eye Skin	Eye Irritation (Category 2) Skin Irritation (Category 2)

GHS Classification and Label Elements

(GHS classification in accordance with 29 CFR 1910 (U.S. OSHA HCS) and EU Regulation (EC) No 1272/2008)

Component	Pictogram	Hazard Statements	Precautionary Statements
ELISA Stop Solution (5.65% Sulfuric Acid)	 Warning	H315 Causes skin irritation. H319 Causes serious eye irritation.	P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves / eye protection / face protection. P305+P351+P338: IF 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 attention.
Supplemental Hazard Statements		1. Follow Universal Precautions when working with this kit. Refer to additional Universal Precaution information in Section 7, Handling and Storage. 2. Maybe harmful if swallowed.	

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
ELISA Stop Solution	Sulfuric Acid	7664-93-9	231-639-5	5.65	11 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. ELISA 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, buffers 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 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. 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 Technical Data Sheet.

Incompatibilities To maintain efficacy, store according to the kit specific Technical Data Sheet.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the components in 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.

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	ELISA Stop Solution (Sulfuric Acid, 5.65%)
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H ₂ O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available

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

Characteristic	ELISA Stop Solution (Sulfuric Acid, 5.65%)
pH	<2
Solubility in Water	Soluble
Appearance and Odor	Clear, colorless; odorless

Section 10 – Stability and Reactivity

Characteristic	ELISA Stop Solution (Sulfuric Acid, 5.65%)
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	No data available
Hazardous Decomposition Products	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
Sulfuric Acid	7664-93-9	WS5600000	Oral LD ₅₀ Rat 2140 mg/kg Inhalation LC ₅₀ Rat (2h) 51 mg/m ³ Dermal LD ₅₀ No data available Eye Irritation = Severe when applied directly to eye. (Standard Draize Test – Rabbit – 250 µg)

Potential Health Effects: ELISA Stop Solution (40-0030) – 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

IARC: Group 1 Carcinogen (Sulfuric Acid Mist)

OSHA: Select carcinogen (Sulfuric Acid Mist)

Reproductive Toxicity

No data available

Teratogenicity

No data available

Section 11 – Toxicological Information (cont'd)

Specified Target Organ General Toxicity (GHS)

Single Exposure (GHS): No data available
Repeated Exposure (GHS): No data available

Synergistic Effects

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 this solution.

Additional Information

Stomach – Irregularities – Based on Human Evidence (Sulfuric Acid)

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

Assessment not available as chemical safety assessment not required or not conducted.

Other Adverse Effects

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

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** ELISA Stop Solution (40-0030): Skin and Eye Irritant
- SARA 302** The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
 Sulfuric Acid CAS #: 7664-93-9 Revision Date: 2007-07-01
- SARA 313** The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
 Sulfuric Acid CAS #: 7664-93-9 Revision Date: 2007-07-01
- SARA 311/312** Sulfuric Acid CAS #: 7664-93-9 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
Sulfuric Acid	7664-93-9	Yes	Yes	Yes	Yes	Yes	Yes

- California Prop 65:** ELISA Stop Solution (40-0030) – **WARNING** – This component contains a chemical known to the State of California to cause birth defects or other reproductive harm.
 Sulfuric Acid CAS #: 7664-93-9 Revision Date: 2007-09-28

Canadian – WHMIS Classification (Raw Material)

Chemical Name	CAS #	Classification
Sulfuric Acid	7664-93-9	E Corrosive - Corrosive to skin

Additional Regulatory Information

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

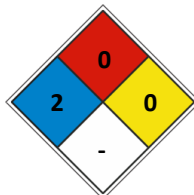
This safety data sheet complies with the requirements of Regulation (EC) No 1907/2006.

Chemical Safety Assessment:

Not completed for the components contained within this kit.

NFPA Kit Classification:

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



Section 16 – Other Information

PREPARED BY: Quidel Corporation
12544 High Bluff Drive, Suite 200, San Diego, CA 92130

SUPERCEDES: September 2, 2016

REVISIONS: Added applicable regulatory references, Universal Precautions statement, removed Canadian IDL and replaced with Canadian WHMIS Classification, and removed HMIS Kit Classification.

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.

SD6039001EN00 (08/17)