

## Section 1 – Product and Company Identification

### 1.1 Manufacturer Information

Quidel Corporation	Phone:	1.800.874.1517	Web:	<a href="http://quidel.com">quidel.com</a>
10165 McKellar Court	Fax:	1.858.453.4338	E-mail:	<a href="mailto:gehs@quidel.com">gehs@quidel.com</a>
San Diego, CA 92121	Emergency # (24-Hour):	1.866.519.4752		

### 1.2 Product Information

Product Name: Sofia Quantitative Vitamin D FIA (Catalog #: 20282)

Intended Use: The Sofia Quantitative Vitamin D FIA is an immunofluorescence-based lateral flow assay designed for the quantitative determination of total 25-OH Vitamin D (25-hydroxy vitamin D) from serum samples.

Components: Individually pouched test cassettes and Extraction Reagent vials

## Section 2 – Hazards Identification

### 2.1 Classification of Substance or Mixture

Component	OSHA Hazards	Target Organs	GHS Classification
Extraction Reagent	Irritant	Eyes, Skin	Eye Irritant (Category 2B) Skin Irritant (Category 2B)

### 2.2 GHS Label Elements & Precautionary Statements

Component	Pictogram	Signal Word	Hazard Statements	Precautionary Statements
Extraction Reagent	None	Warning	H316 Causes mild skin irritation. H320 Causes eye irritation.	P264 Wash exposed skin thoroughly after handling. P280 Wear protective gloves and eye protection. P305+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.

### 2.3 Supplemental Hazard Statements

Supplemental Hazard Statements	P273 Avoid release to the environment.
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## Section 3 – Composition / Information on Ingredients

### 3.1 Mixture

Component Name	Chemical Name	CAS #	EINECS #	Conc. (%)	Volume (mL)
Extraction Reagent	Sodium (meta) Periodate	7790-28-5	232-197-6	4.8	0.6
	Deionized Water	7732-18-5	231-791-2	70	

## Section 4 – First Aid Measures

### 4.1 Description of First Aid Measures

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

*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:* **DO NOT** induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops.

### 4.2 Most important Symptoms and Effects (both acute and delayed)

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

### 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific measures identified.

## Section 5 – Fire Fighting Measures

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

### 5.1 Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

### 5.2 Special Hazards Arising from the Substance or Mixture

Nature of decomposition products not known.

### 5.3 General Fire Hazards

The solution within this kit will not significantly contribute to the intensity of a fire.

### 5.4 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.

### 6.1 Personal Precautions

Use personal protective equipment, including protective gloves and safety glasses when cleaning up spills of this solution. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from spill area.

## Section 6 – Accidental Release Measures (cont'd)

### 6.2 Methods and Materials for Clean-Up

Wipe up with inert absorbent material. Thoroughly wash the area with soap and water after a spill or release clean-up.

### 6.3 Recovery and Neutralization

Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

### 6.4 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

### 7.1 Specific Use:

Refer to product specific package insert. Not for use by the general public.

### 7.2 Precautions for Safe Handling

As with all chemical substances, avoid getting this material ON YOU or IN YOU. Wash exposed areas thoroughly after handling. Do not eat or drink while handling these components. This kit should be handled only by qualified laboratory employees trained on the potential hazards associated with the components within this kit.

### 7.3 Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma potentially used in the 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.

### 7.4 Conditions for Safe Storage

To maintain efficacy, store according to the package insert instructions.

### 7.5 Incompatibilities

No data available

## Section 8 – Exposure Controls and Personal Protection

### 8.1 Exposure Limits

No occupational exposure limit values have been established for the components within this kit.

### 8.2 Exposure Controls:

#### 8.2.1 Engineering Measures

Use with adequate ventilation to minimize potential for worker exposure.

#### 8.2.2 Personal Protective Equipment

*Respiratory Protection:* None needed under normal conditions of use. Perform risk assessment if conditions of use change to determine if respiratory protection is required.

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

*Hand Protection:* Handle with appropriately rated chemical resistant gloves (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.

### 8.2.2 Personal Protective Equipment

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

*Skin / 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.

### 8.2.3 Environmental Exposure Controls

No special environmental controls are required.

## Section 9 – Physical and Chemical Properties

Characteristic	Extraction Reagent
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H <sub>2</sub> 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
pH	4.5
Solubility in Water	Soluble
Appearance and Odor	Slightly pink to purple with no odor

## Section 10 – Stability and Reactivity

Characteristic	Extraction Reagent
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	Organic materials, reducing agents, powdered metals, magnesium
Hazardous Decomposition Products	Under fire conditions – Carbon oxides, Nitrogen oxides (NO <sub>x</sub> ), Sulfur oxides.

## Section 11 – Toxicological Information

### 11.1 Information on Toxicological Effects

#### 11.1.1 Acute Toxicity

*Component Analysis – LD50 / LC50 / Irritation (No data available for this specific extraction solution)*

Chemical Name	CAS #	RTECS #	Information		
Sodium (meta) Periodate	7790-28-5	SD4550000	Oral LD <sub>50</sub>	Rat	264 mg/kg

#### 11.1.2 Potential Health Effects:

*Skin Corrosion/ Irritation:* May cause transient irritation

*Respiratory or Skin Sensitization:* No data available

*Generative Cell Mutagenicity:* No data available

#### 11.1.3 Signs and Symptoms of Exposure

*Inhalation:* No data available

*Serious Eye Damage / Irritation:* No data available

*Skin:* May cause skin irritation.

*Eyes:* Causes eye irritation.

*Ingestion:* May cause irritation if swallowed.

#### 11.1.4 Carcinogenicity

No component within this kit, present at levels greater than or equal to 0.1%, is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.

**11.1.5 Reproductive Toxicity** No data available

**11.1.6 Teratogenicity** No data available

#### 11.1.7 Specified Target Organ Toxicity (STOT)

*Single Exposure* No data available

*Repeated Exposure* No data available

**11.1.8 Aspiration Hazard** No data available

### 11.2 Signs and Symptoms of Exposure Synergistic Effects

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

### 11.3 Additional Information

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

## Section 12 – Ecological Information

**12.1 Ecotoxicity** No data available

**12.2 Persistence and Degradability** No data available

**12.3 Bioaccumulation Potential** No data available

**12.4 Mobility in Soil** No data available

**12.5 PBT and vPvB Assessment** No data available

**12.6 Other Adverse Effects** An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid disposal to the environment.

## Section 13 – Disposal Considerations

### 13.1 Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from working with the components within this kit. Do not discharge the Extraction Reagent into drains, water courses or onto the ground.

### 13.2 Disposal of Product and Contaminated Packaging

Dispose of waste materials in compliance with federal, state and local regulations. If unsure of the applicable regulatory requirements, contact the authorities for information.

## Section 14 – Transportation Information

**14.1 U.S. Department of Transportation (DOT):** This material is not regulated for transport.

**14.2 International Air Transportation (IATA):** This material is not regulated for transport.

**14.3 International Maritime Dangerous Goods (IMDG):** This material is not regulated for transport.

## Section 15 – Regulatory Information

### 15.1 U.S. Federal Regulations

#### 15.1.1 OSHA Hazards

Extraction Reagent: Irritant

#### 15.1.2 SARA 302

No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

#### 15.1.3 SARA 313

This kit does not contain any chemical components with known CAS numbers that exceed threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### 15.1.4 SARA 311/312

Acute Health Hazard (Extraction Reagent)

### 15.2 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 (meta) Periodate	7790-28-5	No	No	No	Yes	Yes	No

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

### 15.3 Canadian - WHMIS Classification

Component	Chemical Name	CAS #	Classification
Extraction Reagent	Sodium (meta) Periodate, 4.8%	7790-28-5	Irritant

## Section 15 – Regulatory Information (cont'd)

### 15.4 Additional Regulatory Information

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

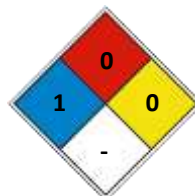
European Union – Regulation (EC) 1907/2006

**Chemical Safety Assessment:**

Not completed for the components within this kit.

**NFPA Classification:**

Health Hazard (blue):	1
Fire Hazard (red):	0
Reactivity Hazard (yellow):	0
Special Hazards (white):	None



## Section 16 – Other Information

**PREPARED BY:** Quidel Corporation  
10165 McKellar Court  
San Diego, CA 92121

**SUPERCEDES:** New

**REVISIONS:** New

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.

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