

Section 1 – Product and Company Identification
1.1 Manufacturer Information

Quidel Corporation	Phone:	1.800.874.1517	Web:	quidel.com
10165 McKellar Court	Fax:	1.858.453.4338	E-mail:	gehs@quidel.com
San Diego, CA 92121	Emergency (24-Hour):	1.866.519.4752		

1.2 Product Information

Product Name: Sofia Quantitative Vitamin D Control Set (Catalog #: 20327)

Intended Use: The Sofia Quantitative Vitamin D Control Set is intended for use as assayed quality control materials to verify the performance of the Sofia Quantitative Vitamin D FIA test system.

Components: Control 1 and Control 2

Section 2 – Hazard Identification
2.1 Classification of the Substance of Mixture

Not a hazardous substance or mixture.

2.2 GHS Label Elements, including Precautionary Statements

Not a hazardous substance or mixture.

2.3 Supplemental Hazard Statements

- Contains potentially infectious materials. Refer to Universal Precautions information in Section 7, Handling and Storage.
- Sodium Azide (<0.1%) is used as a preservative in these controls.
- Streptomycin Sulfate (<0.1%) is used in these controls.
- Avoid disposal of this material down sanitary or industrial plumbing systems.
- Potentially infectious material
- Wash hands thoroughly after handling these Controls. (P264)


Section 3 – Composition / Information on Ingredients
3.1 Mixtures

Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200).

Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Control 1	Human Sourced Material Proprietary neutral non-hazardous buffer	-- --	-- --	20-40 19-59	3 mL
Control 1	Human Sourced Material Proprietary neutral non-hazardous buffer	-- --	-- --	20-40 19-59	3 mL

3.2 No chemicals need to be disclosed according to the applicable regulations for the components in this kit.

Section 4 – First Aid Measures**4.1 Description of First Aid Measures**

- 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.

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

For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 Special Hazards Arising from the Substance or Mixture

Nature of decomposition products not known.

5.3 General Fire Hazards

The components 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

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of any of the components listed in this SDS is unlikely.

6.1 Personal Precautions

Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the Bone Health antibodies or proteins. Avoid breathing vapors, mist or gas. Keep all unnecessary personnel away from the spill area.

6.2 Methods and Materials 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.

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 to the environment must be avoided.

Section 7 – Handling and Storage

7.1 Specific Use For professional use only – Not for use by the general public.

7.2 Precautions for Safe Handling

As with all chemical and biological substances, avoid getting these components ON YOU or IN YOU. Wash exposed areas thoroughly after using these components. Do not eat or drink while using these components. These components should be handled only by qualified clinical or laboratory employees trained on the use of these controls and who are familiar with the potential hazards. Keep out of reach of the general public.

7.3 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.

7.4 Conditions for Safe Storage (including any incompatibilities)

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

7.5 Incompatibilities

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

Section 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits No data available for the Controls in this kit.

8.2 Exposure Controls

Engineering Measures Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection

None needed under normal conditions of use.

Skin 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 these components.

Eye Protection

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

Body Protection

Use body protection appropriate for the task. A laboratory coat is recommended.

Hygiene Measures

Wash hands before use, after use and at the end of the workday.

8.3 Environmental Exposure Controls No special environmental controls are required.

8.4 Special Notes No data available.

Section 9 – Physical and Chemical Properties

Characteristic	Control 1	Control 2
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	No data available	No data available
Solubility in Water	Soluble	Soluble
Appearance and Odor	Clear liquid, Odorless (frozen)	Clear liquid, Odorless (frozen)

Section 10 – Stability and Reactivity

Characteristic	Control 1	Control 2
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 Properties
11.1 Information on Toxicological Effects

Acute Toxicity	No data available
Skin Corrosion / Irritation	No data available
Respiratory or Skin Sensitization	No data available
Generative Cell Mutagenicity	No data available
Carcinogenicity	No component of 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.
Reproductive Toxicity	No data available
Teratogenicity	No data available
Specified Target Organ Toxicity	
<u>Single Exposure:</u>	No data available
<u>Repeated Exposure:</u>	No data available
Aspiration Hazard	No data available
Potential Health Effects	
<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Ingestion:</i>	May be harmful if swallowed.
<i>Skin:</i>	May cause skin irritation upon contact.
<i>Eyes:</i>	May cause eye irritation.

11.2 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 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 Toxicity	No data available
12.2 Persistence and Degradability	No data available
12.3 Bioaccumulative 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 using this kit. Do not discharge any of the controls into drains, water courses or onto the ground.

13.2 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

- | | |
|---|---|
| 14.1 U.S Department of Transportation (DOT) | These components are not regulated for transport. |
| 14.2 International Air Transportation Association (IATA) | These components are not regulated for transport. |
| 14.3 International Maritime Dangerous Goods (IMDG) | These components are not regulated for transport. |

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

- | | |
|---------------------|---|
| OSHA Hazards | None |
| 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:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313. |
| SARA311/312 Hazards | No SARA hazards. |

15.2 State Regulations

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

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
--	-	-	-	-	-	-	-

California Prop 65:



WARNING: This kit contains a chemical (<0.1%) known to the State of California to cause birth defects or other reproductive harm.

Streptomycin Sulphate

CAS-No. 3810-74-0

Revision Date 2007-09-28

15.3 Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
Control 1 (Human Sourced Material)	--	Potentially infectious material
Control 2 (Human Sources Material)	--	Potentially infectious material

Section 15 – Regulatory Information (cont'd)**15.4 Additional Regulatory Information****Safety, Health and Environmental Regulations/Legislation Specific for the Mixture**

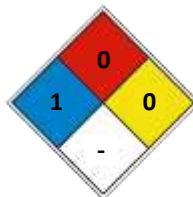
European Union – Regulation (EC) 1907/2006.

Chemical Safety Assessment

Not completed for the components contained within this kit.

NFPA Kit Classification:

Health Hazard (blue): 1
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

SUPERSEDES: --**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.