

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: Thyretain Control Set (Catalog #: 40-TSI.25.v2 and 40-TSI.50.v2)

 Intended Use: Control set for *In Vitro Diagnostic* use with the Thyretain® TSI Reporter BioAssay. The TSI bioassay is for the qualitative detection in serum of thyroid stimulating autoantibodies to the thyroid stimulating hormone (TSH) receptors (TSHRs) on the thyroid.

Components: Positive Control, Negative Control, Reference Control

Section 2 – Hazards Identification

Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Positive Control Negative Control Reference Control	None	None	Not a hazardous substance or mixture.

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
Positive Control Negative Control Reference Control	None Signal Word None	None	P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.
Supplemental Hazard Statements		1. Follow Universal Precautions when working with this kit. 2. Avoid release to the environment. 3. Various antimicrobials are used within the Reference Control, including Penicillin G and Streptomycin Sulfate. Some or all of these antimicrobials may exhibit sensitization or toxicity (e.g., liver) characteristics at low concentrations. 4. Streptomycin Sulfate is suspected of damaging fertility or the unborn child.	

Hazards Not Otherwise Classified (HNOC) or not covered by GHS: None

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Reference Control	Streptomycin Sulfate Penicillin G Sodium Salt	3810-74-0 69-57-8	223-286-0 200-710-2	<0.02	100 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.

<i>If inhaled:</i>	Move the person to fresh air and support breathing as required.
<i>In case of skin contact:</i>	Wash affected area with soap and water. Seek medical advice if irritation develops.
<i>In case of eye contact:</i>	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.
<i>If swallowed:</i>	Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.
<i>Note to Physicians:</i>	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.

<i>Extinguishing Media:</i>	For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
<i>General Fire Hazards:</i>	The components within this kit will not significantly contribute to the intensity of a fire.
<i>Hazardous Combustion Products:</i>	No data available
<i>Fire Fighting Equipment:</i>	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>	Soak 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: For research use only. 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.

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.

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	Reference Control
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
pH	No data available
Solubility in Water	Soluble
Appearance and Odor	Clear solution, colorless, odorless

Section 10 – Stability and Reactivity

Characteristic	Reference Control
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
Streptomycin Sulfate	3810-74-0	No data available	Oral LD ₅₀ Rat 430 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available
Penicillin G	69-57-8	No data available	Oral LD ₅₀ Rat 6,916 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available

Potential Health Effects: Reference Control: Sensitizer

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.

Generative Cell Mutagenicity: No data available

Eyes: May cause serious eye irritation.

Skin or Respiratory Sensitization:

Ingestion: May be harmful if swallowed.

 May cause sensitization by skin contact.

 May cause sensitization by inhalation.

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 ACGIH, IARC, NTP or OSHA.

Reproductive Toxicity

Streptomycin Sulfate: Suspected of damaging fertility or the unborn child.

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.

Synergistic Effects

No data available

Section 11 – Toxicological Information (cont'd)

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.

Reference Control: Liver – Irregularities – Based on Human Evidence (Streptomycin Sulfate)

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. 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, controls, cultures or media 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)	Not regulated for transport.
International Air Transportation (IATA)	Not regulated for transport.
International Maritime Dangerous Goods (IMDG)	Not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards Reference Control: None (Potential sensitizer to susceptible persons.)

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.

Section 15 – Regulatory Information (cont'd)

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.

SARA 311/312 No SARA hazards.

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
Streptomycin Sulfate	3810-74-5	No	No	No	No	No	No
Penicillin G	69-57-8	No	No	No	No	No	No

California Prop 65:

WARNING! The Reference Control contains a chemical known to the State of California to cause cancer.

Streptomycin Sulfate CAS#: 3810-74-5 Revision Date: 2007-09-28 Category: Developmental

Canadian – WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
-	--	--

Additional Regulatory Information

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

Not completed for this components contained within this kit.

Chemical Safety Assessment:

Not completed for this components contained within this kit.

HMIS Kit Classification:

Health: 1
Chronic Health Hazard: *
Flammability: 0
Physical Hazard: 0

NFPA Kit Classification:

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

**Use additional care when handling this kit.*

Section 16 – Other Information

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

SUPERCEDES: SDS-317.4en (v2010May06)

REVISIONS: Update to GHS compliant format along with rebranding from Diagnostic Hybrids to Quidel.

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.