

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: Thyretain TSI Reporter BioAssay (Catalog #: 40-25000.v2 and 40-50000.v2)

Intended Use: Intended for the qualitative detection in serum of thyroid stimulating autoantibodies to the thyroid stimulating hormone (TSH) receptors (TSHRs) on the thyroid.


Components: CHO Mc4 FreshFrozenCells (cc-00xxx), Cell Attachment Solution (40-400200.v2), Growth Medium (40-100200.v2), Reaction Buffer (40-300500.v2), Control Set (40-TSI.xx.v2) and Luciferase Assay Reagent Set (40-E2610.v2).

Section 2 – Hazards Identification

Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Luciferase Substrate (lyophilized)	Irritant	Eyes, Skin, Respiratory	Acute Toxicity (Category 4) Skin Irritation (Category 2) Eye Irritation (Category 2) STOT SE3

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
Luciferase Substrate (lyophilized)	 WARNING	H302 Harmful if swallowed. H315 May cause skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation.	P264 Wash hands thoroughly after handling. P271 Use in a well-ventilated area. P280 Wear protective gloves and safety glasses.

This kit contains material(s) of human and/or animal origin and should be considered as potentially infectious. Universal Precautions should be followed when working with the various components contained within this kit.

Various antimicrobials are used within these cell culture media, including Amphotericin B, Gentamicin, Penicillin G and Streptomycin Sulfate. Some or all of these antimicrobials may exhibit sensitization or toxicity (e.g., liver) characteristics at low concentrations.

The U.S.-origin fetal bovine serum (FBS) and bovine serum albumin (BSA) used within these products, and the bovine-derived trypsin used in the preparation of cell cultures, are fully characterized and tested by the supplier(s) to demonstrate normal and specific levels of serum constituents (of the FBS) and to confirm the absence of *Mycoplasma spp.* and other organisms, in compliance with US-9CFR113.

When working with the Thyretain TSI Reporter BioAssay, we always recommend that employees wear appropriate personal protective equipment (PPE), including gloves, a lab coat and eye protection, and follow good laboratory hygiene practices to avoid any accidental exposure to workplace materials.

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
FreshFrozenCells	Dimethyl Sulfoxide	67-68-5	200-664-3	7.5	0.5 mL/FV
Luciferase Substrate	DL-Dithiothreitol Sodium Hydrosulfite	3483-12-3 7775-14-6	222-468-7 231-890-0	50-75 1-5	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. Treat symptomatically.

<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 (do not swallow). Seek medical advice if irritation develops.

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>	Nature of decomposition products not known.
<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>	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.
<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: 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. 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 within 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.

Additional Reference: Follow standard handling guidelines as detailed in CDC-NIH Manual, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, latest edition.

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 these cultures.

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	FreshFrozenCells	Luciferase Substrate
Boiling Point (C)	No data available	No data available
Melting Point (C)	No data available	No data available

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

Characteristic	FreshFrozenCells	Luciferase Substrate
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	No data available	No data available
Appearance and Odor	Light pink, no odor	Solid, colorless, faint odor

Section 10 – Stability and Reactivity

Characteristic	FreshFrozenCells	Luciferase Substrate
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 Information

Acute Toxicity No data available for the specific Thyretain components contained within this kit for inhalation or dermal exposure.

Potential Health Effects:

<i>Skin Corrosion/Irritation:</i>	No data available	<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin: Eyes:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Ingestion:</i>	May cause eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available		May be harmful if swallowed.

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 IARC, ACGIH, NTP or OSHA.

Reproductive Toxicity No data available **Teratogenicity** No data available

Specified Target Organ General Toxicity (GHS)

<i>Single Exposure (GHS):</i>	No data available
<i>Repeated Exposure (GHS):</i>	No data available

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Synergistic Effects No data available

Additional Information

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

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 product. Do not discharge any of the solutions, reagents, controls or cultures 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	<u>Luciferase Substrate</u> : 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: No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313.
SARA 311/312	No SARA hazards.

Section 15 – Regulatory Information (cont'd)**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
Dimethyl Sulfoxide	67-68-5	No	Yes	No	Yes	No	No
DL-Dithiothreitol	3483-12-3	No	No	No	Yes	No	No
Sodium Hydrosulfite	7775-14-6	No	No	No	Yes	Yes	No

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

Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
Dimethyl Sulfoxide	67-68-5	--

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

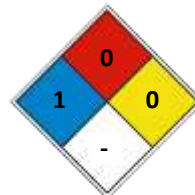
European Union – Regulation (EC) 1907/2006.

Chemical Safety Assessment:

Not completed for the components contained within this kit.

NFPA Kit Classification:

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

**Section 16 – Other Information**

PREPARED BY: Quidel Corporation **SUPERCEDES:** May 4, 2015
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REVISIONS: General formatting throughout the document. Section 7, added Universal Precautions statement; Section 15, updated California Prop 65 statement, updated Canadian WHMIS information, 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.