

**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: InflammaDry External Controls (Catalog #: RPS-DESTD)


Intended Use: External controls to be used with the InflammaDry Test (Catalog #: RPS-ID-20-U and RPS-ID-20) only and are intended to verify that the test reagents are working and that the test is performed correctly.

Components: Positive Control (lyophilized), Negative Control (lyophilized), Diluent

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

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Negative Control (<0.05% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)

**2.2 GHS Label Elements, including Precautionary Statements**

Kit Component	Pictogram	Hazard Statements	Precautionary Statements
Negative Control (<0.05% Proclin 300)	 Warning	H317 May cause an allergic skin reaction.	P264 Wash hands thoroughly after handling. P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P333+P313: If skin irritation or rash occurs: Get medical attention.

**2.3 Supplemental Hazard Statements**

- Refer to Universal Precautions information in Section 7, Handling and Storage.
- Avoid release to the environment.

**Section 3 – Composition / Information on Ingredients**
**3.1 Mixtures**

Kit Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Negative Control	Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	<0.05	

**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 sample diluent. 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**

Refer to product specific package insert. For in vitro diagnostic use.

**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 antibodies and proteins and who are

### Section 7 – Handling and Storage (cont'd)

familiar with the potential hazards. Universal Precautions should be followed when handling and working with these components. 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 specific components within 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	Diluent	Positive Control	Negative Control
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	Neutral	Neutral	Neutral
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Clear, colorless, odorless	White powder, odorless	White powder, odorless

**Section 10 – Stability and Reactivity**

Characteristic	Diluent	Positive Control	Negative Control
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	No data available	No data available	No data available
Conditions to Avoid	No data available	No data available	No data available
Materials to Avoid	No data available	No data available	No data available
Hazardous Decomposition Products	No data available	No data available	No data available

**Section 11 – Toxicological Properties**
**11.1 Information on Toxicological Effects**
**Acute Toxicity**

Chemical Name	CAS #	RTECS #	Information
<b>Mixture for Proclin 300:</b> 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	Oral LD <sub>50</sub> Rat 53 mg/kg Inhalation LC <sub>50</sub> No data available Dermal LD <sub>50</sub> No data available

Skin Corrosion / Irritation May cause irritation of eyes.

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**

Single Exposure: No data available      Repeated Exposure: No data available

Aspiration Hazard No data available

**Potential Health Effects**

*Inhalation:* May cause respiratory tract irritation.      *Skin:* May cause skin irritation upon contact.

*Ingestion:* May be harmful if swallowed.      *Eyes:* May cause serious 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**

Sensitization: Contains a small volume of a very dilute, sensitizing preservative (Proclin 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

**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.  
*Proclin 300 is very toxic to aquatic life with long lasting effects.*

**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 control stocks 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 Negative Control: Sensitizer, 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.
- SARA311/312 Hazards Proclin 300 CAS #: 55965-84-9 Acute Health Hazard

**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
<b>Mixture for Proclin 300:</b> 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	No	No	No	Yes	Yes	No

California Prop 65: None of the components listed in this SDS contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**Section 15 – Regulatory Information (cont'd)**
**15.3 Canadian – WHMIS Classification**

Chemical Name	CAS #	Classification
<b>Mixture for Proclin 300:</b> 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	No data available

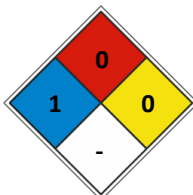
**15.4 Additional Regulatory Information**

**Safety, Health and Environmental Regulations/Legislation Specific for the Mixture** No data available

**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

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**SUPERSEDES:** --

**REVISIONS:** New

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