

Section 1 – Product and Company Identification**1.1 Manufacturer Information**

Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

Phone: 1.800.874.1517
Fax: 1.858.453.4338
Emergency (24-Hour): 1.866.519.4752

Web: quidel.com
E-mail: gehs@quidel.com

1.2 Product Information

Product Name: AdenoPlus (Catalog #: RPS-AD)

Intended Use: A rapid, immunoassay test for the visual, qualitative, *in vitro* detection of Adenoviral antigens (hexon protein) directly from human eye fluid. For *in vitro* diagnostic use only.

Components: Sample Collector, Test Cassette, Buffer Vial

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

- Refer to Universal Precautions information in Section 7, Handling and Storage.
- Sodium azide is used as a preservative (0.1%) in the Buffer Solution. Avoid disposal of this solution down the sanitary or industrial plumbing systems.
- The Dacron® material used in the sampling fleece may cause allergic reactions for some people.

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.

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. 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**

For *in vitro* diagnostic use only. For prescription 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 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	
<i>Respiratory Protection</i>	None needed under normal conditions of use.
<i>Skin Protection</i>	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.
<i>Eye Protection</i>	Wear safety glasses with side shields or goggles to prevent eye contact.
<i>Body Protection</i>	Use body protection appropriate for the task. A laboratory coat is recommended.
<i>Hygiene Measures</i>	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	Buffer Vial
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	9.5
Solubility in Water	Soluble
Appearance and Odor	Clear, colorless, odorless

Section 10 – Stability and Reactivity

Characteristic	Buffer Vial
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 Properties

11.1 Information on Toxicological Effects

Acute Toxicity	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	
<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 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	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
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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.

15.3 Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
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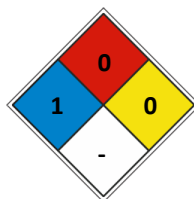
15.4 Additional Regulatory Information

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
12544 High Bluff Drive, Suite 200, San Diego, CA 92130

SUPERSEDES: --
REVISIONS: New

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