

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: D³ DFA Chlamydiae Culture Confirmation Kit (Catalog #: 01-040000)

Intended Use: Confirmation kit is intended for the qualitative identification of Chlamydiae lipopolysaccharide (LPS) in inoculated cell cultures by immunofluorescence using fluoresceinated monoclonal antibodies (MAbs).


Components: Chlamydiae DFA Reagent (01-045005), Chlamydia Antigen Control Slides (01-00011 and 01-00012), 40X PBS Concentrate (01-090025), and Mounting Fluid (01-002007b).

Section 2 – Hazards Identification

Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
40X PBS Concentrate (Sodium Azide, 4%)	Toxic, Irritant	Eyes, Skin	Acute toxicity, Oral (Category 4) Acute aquatic toxicity (Category 3) Skin Irritation (Category 2) Eye Irritation (Category 2A) Chronic aquatic toxicity (Category 3)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
40X PBS Concentrate (Sodium Azide, 4%)		H302 Harmful if swallowed. H315 Causes skin irritation. H320 Causes eye irritation. H412 Harmful to aquatic life with long lasting effects.	P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves and safety glasses. P308+P313: If exposed or concerned – get medical advice/attention. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	Signal Word		
	Warning		
Supplemental Hazard Statements		1. Follow Universal Precautions when working with this kit. 2. Sodium azide is used as a preservative (<0.1%) in the Chlamydiae DFA Reagent and Mounting Fluid. 3. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Avoid disposal of this material down sanitary or industrial plumbing systems. 4. Sodium azide may rapidly be absorbed through the skin. 5. Evans Blue is used in the Chlamydiae DFA Reagent at a concentration of <0.01%. Evans Blue is a possible carcinogen and may cause cancer (IARC Group 3). 6. <u>Chlamydia Antigen Control Slides</u> are microscope slides onto which either cultured <i>non</i> -infected cells or <i>Chlamydia trachomatis</i> -infected cells have been grown then fixed (killed) with acetone; a drying agent is included in the foil envelope to preserve antigen integrity; there is no residual acetone present.	

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
40X PBS Concentrate	Sodium Chloride	7647-14-5	231-598-3	<36	25 mL	Acute Tox. 2; Acute Tox. 1; STOT RE 2; Aquatic Acute 1; Aquatic Chronic 1; H300 +H310, H373, H410
	Sodium Azide	26628-22-8	247-852-1	4		
Mounting Fluid	Glycerol	56-81-5	200-289-5	60	7 mL	--

NOTE: All of the above reagents, buffers, solutions or fluids are considered 'Mixtures'.

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.

- 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.
- Note to Physicians:* 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.

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

- Personal Precautions:* 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.
- Materials and Methods for Clean-Up:* 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.
- Recovery and Neutralization:* Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.

Section 6 – Accidental Release Measures (cont'd)

Environmental Precautions: 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 *In Vitro Diagnostic* use. 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	40X PBS Concentrate
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	7.0-7.6
Solubility in Water	Soluble
Appearance and Odor	Clear liquid, mild odor

Section 10 – Stability and Reactivity

Characteristic	40X PBS Concentrate
Component Stability	Stable
Hazard Reaction Potential	No data available
Conditions to Avoid	No data available
Materials to Avoid	Metals, acids, dimethyl sulfate, halogenated hydrocarbons
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
Sodium Azide	26628-22-8	VY8050000	Oral LD ₅₀ Rabbit 10 mg/kg
			Inhalation LC ₅₀ Rat 37 mg/m ³
			Dermal LD ₅₀ Rabbit 20 mg/kg

Potential Health Effects: 40X PBS Concentrate: Toxic, Irritant

<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:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Eyes:</i>	May cause serious eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May be harmful if swallowed.

Carcinogenicity

Chlamydiae DFA Reagent: Evans Blue IARC Group 3: Not classifiable as to its carcinogenicity to humans.

Reproductive Toxicity No data available

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

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.

40X PBS Concentrate: Liver – irregularities – Based on Human Evidence (Sodium Azide)

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

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
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes	Yes

California Prop 65: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

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 Hazard: 2
 Chronic Health Hazard: *
 Flammability: 0
 Physical Hazard: 0

NFPA Kit Classification:

Health Hazard (blue): 2
 Fire Hazard (red): 0
 Reactivity Hazard (yellow): 0
 Special Hazards (white): 0

**Use additional care when handling this kit.*

Section 16 – Other Information

Text of H-code(s) mentioned in Section 3:

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
H300 + H310	Fatal if swallowed or in contact with skin
H373	May cause damage to organs through prolonged or repeated exposure if swallowed.
H410	Very toxic to aquatic life with long lasting effects.
STOT RE	Specific target organ toxicity - repeated exposure

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

SUPERCEDES: April 27, 2015

REVISIONS: Update Section 14, Transportation information and general formatting.

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.