

SECTION 1: Identification
1.1. Identification

Product form	: Mixture
Product name	: D ³ IFA Enterovirus Identification Kit
Product code	: 01-050000

1.2. Recommended use and restrictions on use

Recommended use	: For medical diagnostic use.
Restrictions on use	: Professional Use of Medical Devices

1.3. Supplier
Manufacturer

Quidel Corporation
 2005 East State Street, Suite 100
 Athens, 45701 - USA
 T 1.800.874.1517 - F 1.740.592.9820
gehs@quidel.com - quidel.com




1.4. Emergency telephone number

Emergency number	: 1.866.519.4752
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SECTION 2: Hazard(s) identification
2.1. Classification of the substance or mixture
GHS US classification

Components	GHS US classification
40X PBS Concentrate (25 mL)	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Aquatic Chronic 2, H411
Mounting Fluid (7 mL)	Acute Tox. 4 (Inhalation:dust,mist), H332

2.2. GHS Label elements, including precautionary statements
GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
40X PBS Concentrate (25 mL)	 	Danger	H302 - Harmful if swallowed H311 - Toxic in contact with skin H411 - Toxic to aquatic life with long lasting effects.	P264 - Wash hands thoroughly after handling. P273 - Avoid release to the environment. P280 - Wear gloves, safety glasses, and lab coat. P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water. P322 - Specific treatment (see supplemental first aid instruction on this label). P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.
Mounting Fluid (7 mL)		Warning	H332 - Harmful if inhaled	P261 - Avoid breathing mist, spray. P280 - Wear gloves, safety glasses, and lab coat. P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing. P322 - Specific treatment (see supplemental first aid instruction on this label). P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
40X PBS Concentrate (25 mL)	sodium azide	26628-22-8	4	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Mounting Fluid (7 mL)	glycerol	56-81-5	60	Acute Tox. 4 (Inhalation:dust,mist), H332
	sodium azide	26628-22-8	0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures
4.1. Description of first aid measures

- First-aid measures general : Call a poison center or a doctor if you feel unwell.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
- First-aid measures after skin contact : Wash skin with plenty of water.
- First-aid measures after eye contact : Rinse eyes with water as a precaution.
- First-aid measures after ingestion : Rinse mouth. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Immediate medical attention and special treatment, if necessary : Treat symptomatically.

SECTION 5: Fire-fighting measures
5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

No additional information available

5.3. Special protective equipment and precautions for fire-fighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures
6.1. Personal precautions, protective equipment and emergency procedures
6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area. Avoid contact with skin, eyes and clothing. Avoid breathing mist, spray.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

- Environmental precautions : Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Collect spillage.
- Methods for cleaning up : Take up liquid spill into absorbent material.
- Other information : Dispose of materials or solid residues at an authorized site.
- Reference to other sections : For further information refer to section 13.

SECTION 7: Handling and storage
7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Do not get in eyes, on skin, or on clothing. Avoid breathing mist, spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store locked up. Store in a well-ventilated place. Keep cool.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Materials for protective clothing:

Lab coat

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear respiratory protection.

Personal protective equipment symbol(s):



Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: 40X PBS, pH 7-7.6
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available

Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
No data available	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Toxic in contact with skin.
Acute toxicity (inhalation)	: Harmful if inhaled.

D3 IFA Enterovirus Identification Kit	
ATE US (oral)	675 mg/kg body weight
ATE US (dermal)	475 mg/kg body weight
ATE US (dust, mist)	2.5 mg/l/4h
40X PBS Concentrate (25 mL)	
ATE US (oral)	675 mg/kg body weight
ATE US (dermal)	475 mg/kg body weight
Mounting Fluid (7 mL)	
ATE US (dust, mist)	2.5 mg/l/4h

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Regional legislation (waste) : Disposal must be done according to official regulations.
 Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
 Sewage disposal recommendations : Disposal must be done according to official regulations.
 Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

Not regulated

International Maritime Dangerous Goods (IMDG)

Not regulated

International Air Transport Association (IATA)

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

D3 IFA Enterovirus Identification Kit

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

40X PBS Concentrate (25 mL)	CAS No	100%
Mounting Fluid (7 mL)	CAS No	100%

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

California Proposition 65 –

This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.