

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**
**1.1. Product identifier**

Product form : Mixture  
 Product name : D<sup>3</sup> IFA Enterovirus Identification Kit  
 Product code : 01-050000

**1.2. Relevant identified uses of the substance or mixture and uses advised against**
**1.2.1. Relevant identified uses**

Industrial/Professional use spec : For in vitro diagnostic use

**1.2.2. Uses advised against**

Restrictions on use : Professional Use of Medical Devices

**1.3. Details of the supplier of the safety data sheet**
**Manufacturer**

Quidel Corporation  
 2005 East State Street, Suite 100  
 45701 Athens - USA  
 T 1.800.874.1517 - F 1.740.592.9820  
[gehs@quidel.com](mailto:gehs@quidel.com) - [quidel.com](http://quidel.com)

**1.4. Emergency telephone number**

Emergency number : 1.866.519.4752

**SECTION 2: Hazards identification**
**2.1. Classification of the substance or mixture**
**Classification according to Regulation (EC) No. 1272/2008 [CLP]**



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


Full text of H- and EUH-statements: see section 16

**Adverse physicochemical, human health and environmental effects**

Toxic in contact with skin. Harmful if inhaled. Harmful if swallowed. Toxic to aquatic life with long lasting effects.

**2.2. Label elements**
**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

| Components                  | Pictograms   | Signal word | Hazard statements   | Precautionary statements  |
|-----------------------------|--|-------------|---|---|
| 40X PBS Concentrate (25 mL) | <br> | Danger      | H302 - Harmful if swallowed.<br>H311 - Toxic in contact with skin.<br>H411 - Toxic to aquatic life with long lasting effects. | P264 - Wash hands thoroughly after handling.<br>P273 - Avoid release to the environment.<br>P280 - Wear gloves, safety glasses, and lab coat.<br>P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.<br>P302+P352 - IF ON SKIN: Wash with plenty of soap and water.<br>P321 - Specific treatment (see supplemental first aid instruction on this label).<br>P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. |

|                              |   |         |                            |   |
|------------------------------|---|---------|----------------------------|---|
| <b>Mounting Fluid (7 mL)</b> |  | Warning | H332 - Harmful if inhaled. | P261 - Avoid breathing mist, spray.<br>P280 - Wear gloves, safety glasses, and lab coat.<br>P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P321 - Specific treatment (see supplemental first aid instruction on this label).<br>P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. |
|------------------------------|---|---------|----------------------------|---|

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

| Name                        | Chemical name | CAS No<br>EC-No. | %   | CLP classification   |
|-----------------------------|---------------|------------------|-----|--|
| 40X PBS Concentrate (25 mL) | sodium azide  | 26628-22-8<br>-  | 4   | Acute Tox. 2 (Oral), H300<br>Acute Tox. 1 (Dermal), H310<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 |
| Mounting Fluid (7 mL)       | glycerol      | 56-81-5<br>-     | 60  | Acute Tox. 4<br>(Inhalation:dust,mist), H332   |
|                             | sodium azide  | 26628-22-8<br>-  | 0.1 | Acute Tox. 2 (Oral), H300<br>Acute Tox. 1 (Dermal), H310<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 |

Full text of H- and EUH-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, both acute and delayed

No additional information available

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

### 5.3. Advice for firefighters

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

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.

### 6.4. 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.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### Materials for protective clothing:

Lab coat

#### Hand protection:

Protective gloves

#### Eye protection:

Safety glasses

#### Skin and body protection:

Wear suitable protective clothing

#### Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

#### Personal protective equipment symbol(s):



**Environmental exposure controls:**

Avoid release to the environment.

**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            |
| Colour  | : No data available |
| Odour   | : No data available |
| Odour threshold                                 | : No data available |
| pH  | : 40X PBS, pH 7-7.6 |
| Relative evaporation rate (butylacetate=1)      | : No data available |
| Melting point                                   | : Not applicable    |
| Freezing point                                  | : No data available |
| Boiling point                                   | : No data available |
| Flash point                                     | : No data available |
| Auto-ignition temperature                       | : No data available |
| Decomposition temperature                       | : No data available |
| Flammability (solid, gas)                       | : Not applicable    |
| Vapour pressure                                 | : No data available |
| Relative vapour 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 |
| Viscosity, kinematic                            | : No data available |
| Viscosity, dynamic                              | : No data available |
| Explosive properties                            | : No data available |
| Oxidising properties                            | : No data available |
| Explosive limits                                | : 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****11.1. Information on toxicological effects**

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

|                     |                      |
|---------------------|----------------------|
| ATE CLP (oral)      | 675 mg/kg bodyweight |
| ATE CLP (dermal)    | 475 mg/kg bodyweight |
| ATE CLP (dust,mist) | 2.5 mg/l/4h          |

|                                   |                  |
|-----------------------------------|------------------|
| Skin corrosion/irritation         | : Not classified |
| Serious eye damage/irritation     | : Not classified |
| Respiratory or skin sensitisation | : 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 |

## SECTION 12: Ecological information

### 12.1. Toxicity

|   |  |
|---|--|
| Ecology - general   | : Toxic to aquatic life with long lasting effects. |
| Hazardous to the aquatic environment, short-term (acute)  | : Not classified                                   |
| Hazardous to the aquatic environment, long-term (chronic) | : 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. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment 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

In accordance with ADR / IMDG / IATA / ADN

### 14.1. UN number

|               |                 |
|---------------|-----------------|
| UN-No. (ADR)  | : Not regulated |
| UN-No. (IMDG) | : Not regulated |
| UN-No. (IATA) | : Not regulated |
| UN-No. (ADN)  | : Not regulated |

### 14.2. UN proper shipping name

|                             |                 |
|-----------------------------|-----------------|
| Proper Shipping Name (ADR)  | : Not regulated |
| Proper Shipping Name (IMDG) | : Not regulated |
| Proper Shipping Name (IATA) | : Not regulated |
| Proper Shipping Name (ADN)  | : Not regulated |

**14.3. Transport hazard class(es)**
**ADR**

Transport hazard class(es) (ADR) : Not regulated

**IMDG**

Transport hazard class(es) (IMDG) : Not regulated

**IATA**

Transport hazard class(es) (IATA) : Not regulated

**ADN**

Transport hazard class(es) (ADN) : Not regulated

**14.4. Packing group**

Packing group (ADR) : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : Not regulated

Packing group (ADN) : Not regulated

**14.5. Environmental hazards**

Dangerous for the environment : Yes

Marine pollutant : Yes

Other information : No supplementary information available

**14.6. Special precautions for user**
**Overland transport**

Not regulated

**Transport by sea**

Not regulated

**Air transport**

Not regulated

**Inland waterway transport**

Not regulated

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable

**SECTION 15: Regulatory information**
**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**
**15.1.1. EU-Regulations**

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

**15.1.2. National regulations**
**Germany**

Regulatory reference : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

 Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)  
 Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

**Netherlands**

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

**Denmark**

Danish National Regulations

 : Young people below the age of 18 years are not allowed to use the product  
 Pregnant/breastfeeding women working with the product must not be in direct contact with the product

**Switzerland**

Chemicals Ordinance (SR 813.11)

: Group 2

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**
**Indication of changes:**

New EU SDS template.

**Abbreviations and acronyms:**

|        |   |
|--------|---|
| ADN    | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways   |
| ADR    | European Agreement concerning the International Carriage of Dangerous Goods by Road               |
| ATE    | Acute Toxicity Estimate   |
| BLV    | Biological limit value  |
| CAS No | Chemical Abstract Service number  |
| CLP    | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008                       |
| DMEL   | Derived Minimal Effect level  |
| DNEL   | Derived-No Effect Level   |
| EC50   | Median effective concentration  |
| EC-No. | European Community number   |
| EN     | European Standard   |
| IATA   | International Air Transport Association   |
| IMDG   | International Maritime Dangerous Goods  |
| LC50   | Median lethal concentration   |
| LD50   | Median lethal dose  |
| LOAEL  | Lowest Observed Adverse Effect Level  |
| NOAEC  | No-Observed Adverse Effect Concentration  |
| NOAEL  | No-Observed Adverse Effect Level  |
| NOEC   | No-Observed Effect Concentration  |
| OEL    | Occupational Exposure Limit   |
| PBT    | Persistent Bioaccumulative Toxic  |
| PNEC   | Predicted No-Effect Concentration   |
| REACH  | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID    | Regulations concerning the International Carriage of Dangerous Goods by Rail                      |
| SDS    | Safety Data Sheet   |
| vPvB   | Very Persistent and Very Bioaccumulative  |
| WGK    | Water Hazard Class  |

Other information

: Please review product insert prior to using this product.

**Full text of H- and EUH-statements:**

|                                     |  |
|-------------------------------------|--|
| Acute Tox. 3 (Dermal)               | Acute toxicity (dermal), Category 3              |
| Acute Tox. 4 (Inhalation:dust,mist) | Acute toxicity (inhalation:dust,mist) Category 4 |
| Acute Tox. 4 (Oral)                 | Acute toxicity (oral), Category 4                |

|                   |   |
|-------------------|---|
| Aquatic Chronic 2 | Hazardous to the aquatic environment – Chronic Hazard, Category 2 |
| H302              | Harmful if swallowed.   |
| H311              | Toxic in contact with skin.                                       |
| H332              | Harmful if inhaled.   |
| H411              | Toxic to aquatic life with long lasting effects.                  |

*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.*