

## 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> Ultra DFA "Family" Screening and ID Kits  
 Product code : 01-010000.v2, 01-010001.v2, 01-010002.v2, 01-010003.v2,  
 01-010004.v2, 01-010005.v2, 01-010006.v2, 01-010007.v2

### 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
Mounting Fluid (15 mL)	Not classified (CLP)
40X Wash Solution Concentrate (25 mL)	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Aquatic Chronic 2, H411



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

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

Toxic in contact with skin. 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 Wash Solution 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 CENTRE or doctor if you feel unwell. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment (see supplemental first aid instruction on this label). 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 ≥ 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 EC-No.	%	CLP classification
40X Wash Solution 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 (15 mL)	glycerol	56-81-5 -	1 – 5	Acute Tox. 4 (Inhalation:dust,mist), H332

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.
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.

##### 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.

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 insufficient ventilation, wear suitable respiratory equipment

##### 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 Wash Solution, 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)	: Not classified

ATE CLP (oral)	675 mg/kg bodyweight
ATE CLP (dermal)	475 mg/kg bodyweight

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
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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 (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.
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.*