

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

Product form : Mixture
 Product name : MicroVue DPD EIA Kit
 Product code : 8007

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 - 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 |
|--------------------------|--|
| Stop Solution (15 mL) | Skin Irrit. 2, H315 Eye Irrit. 2, H319 |
| Substrate Buffer (10 mL) | Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 2, H373 |


Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure. Causes skin irritation. Causes serious eye damage.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

| Components | Pictograms | Signal word | Hazard statements | Precautionary statements |
|-----------------------|---|-------------|---|--|
| Stop Solution (15 mL) |  | Warning | H315 - Causes skin irritation. H319 - Causes serious eye irritation. | P264 - Wash hands thoroughly after handling. P280 - Wear gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. |

| | | | | |
|---------------------------------|---|---------------|--|---|
| Substrate Buffer (10 mL) |  | Danger | H315 - Causes skin irritation. H318 - Causes serious eye damage. H373 - May cause damage to organs through prolonged or repeated exposure. | P260 - Do not breathe mist, spray. P264 - Wash hands thoroughly after handling. P280 - Wear gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313 - If skin irritation occurs: Get medical advice/attention. 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 EC-No. | % | CLP classification |
|--------------------------|------------------|------------------|---------|---|
| Substrate Buffer (10 mL) | Diethanolamine | 111-42-2 - | 10 – 15 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 2, H373 |
| Stop Solution (15 mL) | sodium hydroxide | 1310-73-2 - | 1 – 5 | Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 |

Specific concentration limits:

| Name | Product identifier | Specific concentration limits |
|------------------|---|---|
| sodium hydroxide | (CAS No) 1310-73-2 (EC-No.) 215-185-5 (EC Index-No.) 011-002-00-6 | (0.5 \leq C < 2) Eye Irrit. 2, H319 (0.5 \leq C < 2) Skin Irrit. 2, H315 (2 \leq C < 5) Skin Corr. 1B, H314 (5 \leq C < 100) Skin Corr. 1A, H314 |

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 | : Get medical advice/attention 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. If skin irritation occurs: Get medical advice/attention. |
| First-aid measures after eye contact | : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately. |
| First-aid measures after ingestion | : Call a poison center or a doctor if you feel unwell. |

4.2. Most important symptoms and effects, both acute and delayed

| | |
|-------------------------------------|---------------------------|
| Symptoms/effects after skin contact | : Irritation. |
| Symptoms/effects after eye contact | : Serious damage to eyes. |

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. Do not breathe mist, spray. Avoid contact with skin and eyes.

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

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 breathe mist, spray. Avoid contact with skin and eyes.

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 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

| sodium hydroxide (1310-73-2) | | |
|------------------------------|---------------------|---------------------|
| Belgium | OEL TWA | 2 mg/m ³ |
| France | VME (OEL TWA) | 2 mg/m ³ |
| United Kingdom | WEL STEL (OEL STEL) | 2 mg/m ³ |
| USA - ACGIH | ACGIH OEL C | 2 mg/m ³ |
| USA - OSHA | Local name | Sodium hydroxide |
| USA - OSHA | OSHA PEL TWA [1] | 2 mg/m ³ |

| diethanolamine (111-42-2) | | |
|---------------------------|---------------------|--|
| Belgium | OEL TWA | 2 mg/m ³ |
| Belgium | OEL TWA [ppm] | 0.46 ppm |
| France | VME (OEL TWA) | 15 mg/m ³ |
| France | VME (OEL TWA) [ppm] | 3 ppm |
| USA - ACGIH | ACGIH OEL TWA | 1 mg/m ³ (Inhalable fraction and vapor) |

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 | : Stop Solution, pH<13 |
| 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) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

| diethanolamine (111-42-2) | |
|----------------------------------|---------------------|
| LD50 oral rat | 620 mg/kg (Rat) |
| LD50 dermal rabbit | 7640 mg/kg (Rabbit) |

Skin corrosion/irritation : Causes skin irritation.

Serious eye damage/irritation : Causes serious eye damage.

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 : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

SECTION 12: Ecological information
12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

| sodium hydroxide (1310-73-2) | |
|-------------------------------------|--|
| LC50 - Fish [1] | 45.4 mg/l (Other, 96 h, Salmo gairdneri, Static system, Fresh water, Experimental value) |
| EC50 - Crustacea [1] | 40.4 mg/l (Other, 48 h, Ceriodaphnia sp., Experimental value) |

| diethanolamine (111-42-2) | |
|----------------------------------|--|
| LC50 - Fish [1] | 1664 mg/l (96 h, Pimephales promelas, Static system) |
| EC50 - Crustacea [1] | 55 mg/l (48 h, Daphnia magna) |
| EC50 72h - Algae [1] | 75 mg/l (Scenedesmus subspicatus) |

12.2. Persistence and degradability
sodium hydroxide (1310-73-2)

| | |
|---------------------------------|-----------------------------------|
| Persistence and degradability | Biodegradability: not applicable. |
| Biochemical oxygen demand (BOD) | Not applicable (inorganic) |
| Chemical oxygen demand (COD) | Not applicable (inorganic) |
| ThOD | Not applicable (inorganic) |

diethanolamine (111-42-2)

| | |
|---------------------------------|--|
| Persistence and degradability | Biodegradable in the soil. Readily biodegradable in water. |
| Biochemical oxygen demand (BOD) | 0.22 g O ₂ /g substance |
| Chemical oxygen demand (COD) | 1.52 g O ₂ /g substance |
| ThOD | 2.13 g O ₂ /g substance |
| BOD (% of ThOD) | 0.1 |

12.3. Bioaccumulative potential
sodium hydroxide (1310-73-2)

| | |
|---------------------------|----------------------|
| Bioaccumulative potential | Not bioaccumulative. |
|---------------------------|----------------------|

diethanolamine (111-42-2)

| | |
|---|------------------------------------|
| Partition coefficient n-octanol/water (Log Pow) | -2.18 – -1.43 (Experimental value) |
| Bioaccumulative potential | Not bioaccumulative. |

12.4. Mobility in soil
sodium hydroxide (1310-73-2)

| | |
|----------------|--|
| Ecology - soil | No (test) data on mobility of the substance available. |
|----------------|--|

12.5. Results of PBT and vPvB assessment
Component

| | |
|------------------------------|---|
| diethanolamine (111-42-2) | This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII |
| sodium hydroxide (1310-73-2) | This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII |

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 | : No |
| Marine pollutant | : No |
| 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 |
|-----------------------------|---|

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. 2 (Oral) | Acute toxicity (oral), Category 2 |

| | |
|---------------------|--|
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| Aquatic Acute 1 | Hazardous to the aquatic environment – Acute Hazard, Category 1 |
| Aquatic Chronic 1 | Hazardous to the aquatic environment – Chronic Hazard, Category 1 |
| Eye Dam. 1 | Serious eye damage/eye irritation, Category 1 |
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| H290 | May be corrosive to metals. |
| H300 | Fatal if swallowed. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| Met. Corr. 1 | Corrosive to metals, Category 1 |
| Skin Corr. 1A | Skin corrosion/irritation, Category 1, Sub-Category 1A |
| Skin Corr. 1B | Skin corrosion/irritation, Category 1, Sub-Category 1B |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| STOT RE 2 | Specific target organ toxicity – Repeated exposure, Category 2 |

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.