# MicroVue CIC-Raji Cell Replacement EIA Kit

Safety Data Sheet

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

Issue date: 01/21/2022 Supersedes: 11/14/2017 Version: 1.0

## SECTION 1: Identification

### 1.1. Identification

Product form : Mixture

Product name : MicroVue CIC-Raji Cell Replacement EIA Kit

Product code : A002

### 1.2. Recommended use and restrictions on use

Recommended use : For in vitro 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
qehs@quidel.com - quidel.com

### 1.4. Emergency telephone number

Emergency number : 1.866.519.4752

## SECTION 2: Hazard(s) identification

### 2.1. Classification of the substance or mixture

**GHS US classification**

| Components | GHS US classification |
|---|---|
| Specimen Diluent (50 mL) | Skin Sens. 1, H317 |
| CIC-Raji Confirmation Diluent (12 mL) | Skin Sens. 1, H317 |
| 20X Wash Solution Concentrate (50 mL) | Skin Sens. 1, H317 |
| Stop Solution (6 mL) | Skin Corr. 1, H314<br>Eye Dam. 1, H318 |
| Substrate Diluent (25 mL) | Skin Irrit. 2, H315<br>Eye Irrit. 2, H319 |

### 2.2. GHS Label elements, including precautionary statements

**GHS US labeling**

| Components | Pictograms | Signal word | Hazard statements | Precautionary statements |
|---|---|---|---|---|
| **Specimen Diluent (50 mL)** |  | Warning | H317 - May cause an allergic skin reaction | P280 - Wear gloves, safety glasses, and lab coat.<br>P302+P352 - If on skin: Wash skin thoroughly with mild soap and water.<br>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.<br>P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations. |
| **CIC-Raji Confirmation Diluent (12 mL)** |  | Warning | H317 - May cause an allergic skin reaction | P280 - Wear gloves, safety glasses, and lab coat.<br>P302+P352 - If on skin: Wash skin thoroughly with mild soap and water.<br>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.<br>P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations. |

| | | | | |
|---|---|---|---|---|
| **20X Wash Solution Concentrate (50 mL)** |  | Warning | H317 - May cause an allergic skin reaction | P280 - Wear gloves, safety glasses, and lab coat.<br>P302+P352 - If on skin: Wash skin thoroughly with mild soap and water.<br>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.<br>P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations. |
| **Stop Solution (6 mL)** |  | Danger | H314 - Causes severe skin burns and eye damage<br>H318 - Causes serious eye damage | P260 - Do not breathe 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>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P337+P313 - If eye irritation persists: Get medical advice/attention.<br>P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations. |
| **Substrate Diluent (25 mL)** |  | Warning | H315 - Causes skin irritation<br>H319 - Causes serious eye irritation | P280 - Wear gloves, safety glasses, and lab coat.<br>P302+P352 - If on skin: Wash skin thoroughly with mild soap and water.<br>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.<br>P337+P313 - If eye irritation persists: Get medical advice/attention.<br>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 |
|---|---|---|---|---|
| 1. Specimen Diluent (50 mL)<br>2. CIC-Raji Confirmation Diluent (12 mL)<br>3. 20X Wash Solution Concentrate (50 mL) | *Mixture for ProClin 300:*<br>5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) | 55965-84-9 | 0.035 | Acute Tox. 3 (Oral), H301<br>Acute Tox. 3 (Dermal), H311<br>Acute Tox. 3 (Inhalation), H331<br>Skin Corr. 1B, H314<br>Skin Sens. 1, H317<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 |
| Stop Solution (6 mL) | oxalic acid, dihydrate | 6153-56-6 | 1 – 5 | Acute Tox. 4 (Oral), H302<br>Skin Corr. 1, H314<br>Eye Dam. 1, H318 |
| Substrate Diluent (25 mL) | citric acid, monohydrate | 5949-29-1 | 1 – 5 | Skin Corr. 1, H314<br>Eye Dam. 1, H318 |

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 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 or rash 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 (acute and delayed)

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Serious damage to eyes.

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 and eyes. 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

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. Avoid breathing 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.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

| oxalic acid, dihydrate (6153-56-6) | | |
|---|---|---|
| ACGIH | ACGIH OEL TWA | 1 mg/m³ |
| ACGIH | ACGIH OEL STEL | 2 mg/m³ |

### 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:**

In case of insufficient ventilation, wear suitable respiratory equipment

**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 | : | Stop Solution, pH <2 |
| 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 availableViscosity, 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) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

| mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|---|---|
| LD50 oral rat | 53 mg/kg (Rat, Literature study) |
| ATE US (oral) | 53 mg/kg body weight |
| ATE US (dermal) | 300 mg/kg body weight |
| ATE US (gases) | 700 ppmV/4h |
| ATE US (vapors) | 3 mg/l/4h |
| ATE US (dust, mist) | 0.5 mg/l/4h |

| citric acid, monohydrate (5949-29-1) | |
|---|---|
| LD50 dermal rat | > 2000 mg/kg body weight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male/female, Experimental value) |

| oxalic acid, dihydrate (6153-56-6) | |
|---|---|
| LD50 oral rat | 475 mg/kg body weight (Rat, Male, Experimental value, Anhydrous form, Oral) |
| LD50 dermal rabbit | 20000 mg/kg body weight (Rabbit, Experimental value, Anhydrous form, Dermal) |
| ATE US (oral) | 475 mg/kg body weight |
| ATE US (dermal) | 20000 mg/kg body weight |

Skin corrosion/irritation : Causes skin irritation.

Serious eye damage/irritation : Causes serious eye damage.

Respiratory or skin sensitization : May cause an allergic skin reaction.

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

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Serious damage to eyes.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

| mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|---|---|
| LC50 - Fish [1] | 0.28 mg/l (96 h, Lepomis macrochirus, Literature) |
| EC50 - Crustacea [1] | 0.16 mg/l (48 h, Daphnia magna, Literature) |

| citric acid, monohydrate (5949-29-1) | |
|---|---|
| LC50 - Fish [1] | 440 – 760 mg/l (Equivalent or similar to OECD 203, 48 h, Leuciscus idus, Static system, Fresh water, Experimental value) |

| citric acid, monohydrate (5949-29-1) | |
|---|---|
| EC50 - Crustacea [1] | 1535 mg/l (Other, 24 h, Daphnia magna, Static system, Fresh water, Experimental value) |

| oxalic acid, dihydrate (6153-56-6) | |
|---|---|
| LC50 - Fish [1] | 160 mg/l (48 h, Leuciscus idus, Static system, Fresh water, Experimental value, Anhydrous form) |
| LC50 - Other aquatic organisms [1] | 5330 mg/l (96 h, Xenopus laevis, Fresh water, Experimental value, Anhydrous form) |
| EC50 - Crustacea [1] | 162.2 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Fresh water, Experimental value, Anhydrous form) |

### 12.2. Persistence and degradability

| mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|---|---|
| Biochemical oxygen demand (BOD) | Not applicable |
| Chemical oxygen demand (COD) | Not applicable |
| ThOD | Not applicable |
| BOD (% of ThOD) | Not applicable |

| citric acid, monohydrate (5949-29-1) | |
|---|---|
| Persistence and degradability | Biodegradable in the soil. Readily biodegradable in water. |
| Biochemical oxygen demand (BOD) | 0.481 g $O_2$/g substance |
| Chemical oxygen demand (COD) | 0.665 g $O_2$/g substance |

| oxalic acid, dihydrate (6153-56-6) | |
|---|---|
| Persistence and degradability | Biodegradable in the soil. Readily biodegradable in water. Readily biodegradable in water in anaerobic conditions. |

### 12.3. Bioaccumulative potential

| mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|---|---|
| Bioaccumulative potential | Not established. |

| citric acid, monohydrate (5949-29-1) | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | -1.8 – -1.55 (Anhydrous form, Experimental value) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

| oxalic acid, dihydrate (6153-56-6) | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | -1.7 (Anhydrous form, Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 23 °C) |
| Bioaccumulative potential | Not bioaccumulative. |

### 12.4. Mobility in soil

| mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|---|---|
| Ecology - soil | No (test)data on mobility of the components available. |

| citric acid, monohydrate (5949-29-1) | |
|---|---|
| Ecology - soil | No (test)data on mobility of the substance available. |

| oxalic acid, dihydrate (6153-56-6) | |
|---|---|
| Surface tension | 70.1 N/m (25 °C, 0.015 mol/l) |
| Ecology - soil | No (test)data on mobility of the substance 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

**MicroVue CIC-Raji Cell Replacement EIA 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:

| | | |
|---|---|---|
| mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) | CAS No 55965-84-9 | < 1% |
| citric acid, monohydrate | CAS No 5949-29-1 | 1 – 5% |
| oxalic acid, dihydrate | CAS No 6153-56-6 | 1 – 5% |

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

**mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9)**

Listed on the Canadian DSL (Domestic Substances List)

**citric acid, monohydrate (5949-29-1)**

Listed on the Canadian DSL (Domestic Substances List)

**oxalic acid, dihydrate (6153-56-6)**

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

#### EU-Regulations

No additional information available

#### National regulations

**oxalic acid, dihydrate (6153-56-6)**

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

### 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.*