

SECTION 1: Identification
1.1. Identification

Product form : Mixture
 Product name : MicroVue CIC-C1q
 Product code : A001

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

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
Substrate Diluent (25 mL)	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Stop Solution (6 mL)	Skin Corr. 1, H314 Eye Dam. 1, H318
20X Wash Solution Concentrate (50 mL)	Skin Sens. 1, H317
Hydrating Reagent (25 mL)	Skin Sens. 1, H317
Confirmation Diluent (10 mL)	Eye Irrit. 2A, H319 Skin Sens. 1, H317 Aquatic Acute 3, H402 Aquatic Chronic 3, H412

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	P261 - Avoid breathing mist, spray. P280 - Wear gloves and safety glasses when handling this component. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. 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 H319 - Causes serious eye irritation	P264 - Wash hands thoroughly after handling P280 - Wear gloves and safety glasses when handling this component. P302+P352 - If on skin: Wash skin thoroughly with mild 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: Dispose in a safe manner in accordance with local/national regulations
Stop Solution (6 mL)		Danger	H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage	P260 - Do not breathe mist, spray. P264 - Wash hands thoroughly after handling P280 - Wear gloves and safety glasses when handling this component. P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting. P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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	P261 - Avoid breathing mist, spray. P280 - Wear gloves and safety glasses when handling this component. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations
Hydrating Reagent (25 mL)		Warning	H317 - May cause an allergic skin reaction	P261 - Avoid breathing mist, spray. P280 - Wear gloves and safety glasses when handling this component. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations
Confirmation Diluent (10 mL)		Warning	H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation H402 - Harmful to aquatic life	P261 - Avoid breathing mist, spray. P264 - Wash hands thoroughly after handling P273 - Avoid release to the environment. P280 - Wear gloves and safety glasses when handling this component.

			H412 - Harmful to aquatic life with long lasting effects	P302+P352 - If on skin: Wash skin thoroughly with mild 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. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations
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SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Specimen Diluent (50 mL)	<i>Mixture for Proclin 300:</i> 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	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Substrate Diluent (25 mL)	citric acid, monohydrate	5949-29-1	1 – 5	Skin Corr. 1, H314 Eye Dam. 1, H318
Stop Solution (6 mL)	oxalic acid, dihydrate	6153-56-6	1 – 5	Acute Tox. 4 (Oral), H302 Skin Corr. 1, H314 Eye Dam. 1, H318
20X Wash Solution Concentrate (50 mL)	<i>Mixture for Proclin 300:</i> 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	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Hydrating Reagent (25 mL)	<i>Mixture for Proclin 300:</i> 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	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Confirmation Diluent (10 mL)	<i>Mixture for Proclin 300:</i> 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	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 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

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|---------------------------------------|--|
| 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. Take off contaminated clothing. 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/doctor/physician if you feel unwell. |

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

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|-------------------------------------|--|
| 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

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. Avoid contact with skin and eyes. Wear personal protective equipment. Avoid breathing spray, mist.
 Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. 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/m ³
ACGIH	ACGIH OEL STEL	2 mg/m ³

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 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) : 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 : Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

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)
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 Transportation Association (IATA)

Not regulated

SECTION 15: Regulatory information
15.1. US Federal regulations
MicroVue CIC-C1q

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:

<i>Mixture for Proclin 300:</i> 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.