

SECTION 1: Identification
1.1. Identification

Product form : Mixture
 Product name : MicroVue CH50 Eq EIA
 Product code : A018

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
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	Skin Sens. 1, H317
20X Wash Solution Concentrate	Skin Sens. 1, H317
Stop Solution	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
TMB Substrate	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Eye Dam. 1, H318 Repr. 1B, H360

2.2. GHS Label elements, including precautionary statements
GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Specimen Diluent		Warning	H317 - May cause an allergic skin reaction	P280 - Wear gloves, safety glasses, and lab coat. 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.
20X Wash Solution Concentrate		Warning	H317 - May cause an allergic skin reaction	P280 - Wear gloves, safety glasses, and lab coat. 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.

Stop Solution		Danger	H290 - May be corrosive to metals H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage	P260 - Do not breathe mist, spray. P280 - Wear gloves, safety glasses, and lab coat. 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. P321 - Specific treatment: Seek medical attention if ill effect develops. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.
TMB Substrate		Danger	H225 - Highly flammable liquid and vapor H315 - Causes skin irritation H318 - Causes serious eye damage H360 - May damage fertility or the unborn child	P264 - Wash hands thoroughly after handling. P280 - Wear gloves, safety glasses, and lab coat. 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. 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 2. 20X Wash Solution Concentrate	<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	0.035	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
Stop Solution	hydrochloric acid ... %	7647-01-0	1 – 5	Met. Corr. 1, H290 Skin Corr. 1, H314 Eye Dam. 1, H318 STOT SE 3, H335
TMB Substrate	1-ethylpyrrolidin-2-one	2687-91-4	1 – 5	Flam. Liq. 4, H227 Eye Dam. 1, H318 Repr. 1B, H360
	1-methyl-2-pyrrolidone	872-50-4	1 – 10	Flam. Liq. 4, H227 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 1B, H360 STOT SE 3, H335
	acetone	67-64-1	1 – 10	Flam. Liq. 2, H225 Eye Irrit. 2A, H319 STOT SE 3, H336

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 general	: IF exposed or concerned: Get medical advice/attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Rinse skin with water/shower. 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 (acute and delayed)

Symptoms/effects after skin contact : Irritation.
 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

Fire hazard : Highly flammable liquid and vapor.

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 : No open flames, no sparks, and no smoking. Only qualified personnel equipped with suitable protective equipment may intervene. 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. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.
 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. Obtain special instructions before use. Avoid contact with skin and eyes. 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

Technical measures : Ground/bond container and receiving equipment.
 Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store in corrosive resistant container with a resistant inner liner. Keep only in original container. Store locked up.
 Incompatible materials : Metals.

SECTION 8: Exposure controls/personal protection
8.1. Control parameters

1-methyl-2-pyrrolidone (872-50-4)		
ACGIH	BEI	100 mg/l Parameter: 5-Hydroxy-N-methyl-2-pyrrolidone - Medium: urine - Sampling time: End of shift
acetone (67-64-1)		
ACGIH	ACGIH OEL TWA [ppm]	250 ppm
ACGIH	ACGIH OEL STEL [ppm]	500 ppm

hydrochloric acid ... % (7647-01-0)		
OSHA	OSHA PEL C	7 mg/m ³
OSHA	OSHA PEL C [ppm]	5 ppm
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

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:

Wear respiratory protection.

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
 Appearance : EIA Kit
 Color : No data available
 Odor : Odorless
 Odor threshold : No data available
 pH : Stop Soluton, pH <1
 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

Highly flammable liquid and vapor.

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

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

Metals.

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

1-ethylpyrrolidin-2-one (2687-91-4)	
LD50 oral rat	3200 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral)
LD50 dermal rat	> 2000 mg/kg body weight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal)
LC50 Inhalation - Rat	> 5.1 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol))
ATE US (oral)	3200 mg/kg body weight
1-methyl-2-pyrrolidone (872-50-4)	
LD50 oral rat	4150 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral, 14 day(s))
LD50 dermal rat	> 5000 mg/kg body weight (Equivalent or similar to OECD 402, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s))
LC50 Inhalation - Rat	> 5.1 mg/l air (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol), 14 day(s))
ATE US (oral)	4150 mg/kg body weight
acetone (67-64-1)	
LD50 oral rat	5800 mg/kg (Equivalent or similar to OECD 401, Rat, Female, Experimental value)
LD50 dermal rabbit	20000 mg/kg (Equivalent or similar to OECD 402, Rabbit, Male, Experimental value)
LC50 Inhalation - Rat	76 mg/l (Other, 4 h, Rat, Female, Experimental value)
ATE US (oral)	5800 mg/kg body weight
ATE US (dermal)	20000 mg/kg body weight
ATE US (vapors)	76 mg/l/4h

acetone (67-64-1)	
ATE US (dust, mist)	76 mg/l/4h
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
hydrochloric acid ... % (7647-01-0)	
IARC group	3 - Not classifiable
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
1-methyl-2-pyrrolidone (872-50-4)	
STOT-single exposure	May cause respiratory irritation.
acetone (67-64-1)	
STOT-single exposure	May cause drowsiness or dizziness.
hydrochloric acid ... % (7647-01-0)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects after skin contact	: Irritation.
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.

1-ethylpyrrolidin-2-one (2687-91-4)	
LC50 - Fish [1]	> 465 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Brachydanio rerio, Static system, Fresh water, Experimental value, Nominal concentration)
EC50 - Crustacea [1]	> 104 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect)
1-methyl-2-pyrrolidone (872-50-4)	
LC50 - Fish [1]	> 500 mg/l (96 h, Oncorhynchus mykiss, Static system, Fresh water, Experimental value)
EC50 - Crustacea [1]	1107 mg/l (EPA 660/3 - 75/009, 96 h, Palaemonetes vulgaris, Static system, Salt water, Experimental value)
EC50 - Crustacea [2]	> 1000 mg/l (DIN 38412-11, 24 h, Daphnia magna, Static system, Fresh water, Experimental value)
acetone (67-64-1)	
LC50 - Fish [1]	5540 mg/l (EU Method C.1, 96 h, Salmo gairdneri, Static system, Fresh water, Experimental value)

12.2. Persistence and degradability

1-ethylpyrrolidin-2-one (2687-91-4)	
Persistence and degradability	Readily biodegradable in water.
1-methyl-2-pyrrolidone (872-50-4)	
Persistence and degradability	Biodegradable in the soil. Readily biodegradable in water.
Biochemical oxygen demand (BOD)	1.07 g O ₂ /g substance
Chemical oxygen demand (COD)	1.56 g O ₂ /g substance
ThOD	1.9 g O ₂ /g substance
BOD (% of ThOD)	0.56

acetone (67-64-1)	
Persistence and degradability	Biodegradable in the soil. Biodegradable in the soil under anaerobic conditions. Readily biodegradable in water.
Biochemical oxygen demand (BOD)	1.43 g O ₂ /g substance
Chemical oxygen demand (COD)	1.92 g O ₂ /g substance
ThOD	2.2 g O ₂ /g substance
BOD (% of ThOD)	0.872 (20 day(s), Literature study)

hydrochloric acid ... % (7647-01-0)	
Persistence and degradability	Biodegradability: not applicable.

12.3. Bioaccumulative potential

1-ethylpyrrolidin-2-one (2687-91-4)	
Partition coefficient n-octanol/water (Log Pow)	-0.2 (Experimental value, EU Method A.8: Partition Coefficient, 23 °C)
Bioaccumulative potential	Not bioaccumulative.

1-methyl-2-pyrrolidone (872-50-4)	
BCF - Other aquatic organisms [1]	3 (Calculated value)
Bioaccumulative potential	Not bioaccumulative.

acetone (67-64-1)	
BCF - Fish [1]	0.69 (Pisces)
BCF - Other aquatic organisms [1]	3 (BCFWIN, Calculated value)
Partition coefficient n-octanol/water (Log Pow)	-0.24 (Test data)
Bioaccumulative potential	Not bioaccumulative.

hydrochloric acid ... % (7647-01-0)	
Bioaccumulative potential	Does not contain bioaccumulative component(s).

12.4. Mobility in soil

1-ethylpyrrolidin-2-one (2687-91-4)	
Surface tension	0.069 N/m (20 °C, 1 g/l, OECD 115: Surface Tension of Aqueous Solutions)
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.6 (log Koc, PCKOCWIN v1.66, Calculated value)
Ecology - soil	Low potential for adsorption in soil. Highly mobile in soil.

1-methyl-2-pyrrolidone (872-50-4)	
Surface tension	0.407 N/m
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.32 (log Koc, Calculated value)
Ecology - soil	Highly mobile in soil.

acetone (67-64-1)	
Surface tension	0.0237 N/m
Ecology - soil	No (test)data on mobility of the substance available.

hydrochloric acid ... % (7647-01-0)	
Ecology - soil	No (test)data on mobility of the components available. May be harmful to plant growth, blooming and fruit formation.

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.
Additional information	: Flammable vapors may accumulate in the container.
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 CH50 Eq EIA

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

1-ethylpyrrolidin-2-one	CAS No 2687-91-4	1 – 5%
1-methyl-2-pyrrolidone	CAS No 872-50-4	1 – 10%
acetone	CAS No 67-64-1	1 – 10%
hydrochloric acid ... %	CAS No 7647-01-0	1 – 5%

Contains chemical(s) subject to TSCA 12b export notification if product is shipped outside the U.S

1-methyl-2-pyrrolidone	CAS No 872-50-4	1 – 10%
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Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.

1-methyl-2-pyrrolidone	CAS No 872-50-4	1 – 10%
hydrochloric acid ... %	CAS No 7647-01-0	1 – 5%

1-ethylpyrrolidin-2-one (2687-91-4)

EPA TSCA Regulatory Flag	SP - SP - indicates a substance that is identified in a proposed Significant New Use Rule.
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1-methyl-2-pyrrolidone (872-50-4)

EPA TSCA Regulatory Flag	R - R - indicates a substance that is the subject of a TSCA section 6 risk management rule.
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acetone (67-64-1)

CERCLA RQ	5000 lb
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hydrochloric acid ... % (7647-01-0)

Listed on EPA Hazardous Air Pollutant (HAPS)

CERCLA RQ	5000 lb
RQ (Reportable quantity, section 304 of EPA's List of Lists)	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb

15.2. International regulations

CANADA

1-ethylpyrrolidin-2-one (2687-91-4)

Listed on the Canadian DSL (Domestic Substances List)

1-methyl-2-pyrrolidone (872-50-4)

Listed on the Canadian DSL (Domestic Substances List)

acetone (67-64-1)

Listed on the Canadian DSL (Domestic Substances List)

hydrochloric acid ... % (7647-01-0)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations



MicroVue CH50 Eq EIA

Safety Data Sheet

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

Revision date: 12/20/2021 Supersedes: 11/14/2017 Version: 1.0

hydrochloric acid ... % (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active
Listed on INSQ (Mexican National Inventory of Chemical Substances)

15.3. US State regulations

WARNING: This product can expose you to 1-methyl-2-pyrrolidone, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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.