SECTION 1: Identification

1.1. Identification

Product form : Mixture

Product name : MicroVue BAP EIA Kit

Product code : 8012

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
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
Stop Solution (15 mL)	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Substrate Buffer (10 mL)	Not classified (GHS US)

2.2. GHS Label elements, including precautionary statements

GHS US labeling

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 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.

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Stop Solution (15 mL)	sodium hydroxide	1310-73-2	1 – 5	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Substrate Buffer (10 mL)	2-amino-2-methylpropanol	124-68-5	1 – 5	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Aquatic Chronic 3, H412

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 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. If eye irritation persists: Get medical advice/attention.

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 : Eye irritation.

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.

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 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

sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL C	2 mg/m³
OSHA	OSHA PEL TWA [1]	2 mg/m³
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:

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 <13
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

2-amino-2-methylpropanol (124-68-5)	
LD50 oral rat	2900 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Male, Experimental value, Oral, 14 day(s))
LD50 dermal rabbit	> 2000 mg/kg body weight (Equivalent or similar to OECD 402, 24 h, Rabbit, Male / female, Experimental value, Dermal, 14 day(s))
ATE US (oral)	2900 mg/kg body weight

Skin corrosion/irritation	:	Causes skin irritation.
Serious eye damage/irritation	:	Causes serious eye irritation.
Respiratory or skin sensitization	:	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
Viscosity, kinematic	:	No data available
Symptoms/effects after skin contact	:	Irritation.
Symptoms/effects after eye contact	:	Eye irritation.

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.

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)

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)

2-amino-2-methylpropanol (124-68-5)	
Persistence and degradability	Readily biodegradable in water.

12.3. Bioaccumulative potential

sodium hydroxide (1310-73-2)	
Bioaccumulative potential	Not bioaccumulative.

2-amino-2-methylpropanol (124-68-5)	
BCF - Fish [1]	< 1 (3 day(s), Leuciscus idus, Static system, Fresh water, Experimental value)
Partition coefficient n-octanol/water (Log Pow)	-0.63 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

12.4. Mobility in soil

sodium hydroxide (1310-73-2)	
Ecology - soil	No (test)data on mobility of the substance available.

2-amino-2-methylpropanol (124-68-5)	
Surface tension	58.4 mN/m (25 °C, 10 %)
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.083 – 0.404 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Highly mobile in soil.

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 BAP 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:

sodium hydroxide	CAS No 1310-73-2	1 – 5%
2-amino-2-methylpropanol	CAS No 124-68-5	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.

sodium hydroxide (1310-73-2)	
CERCLA RQ	1000 lb

15.2. International regulations

CANADA

sodium hydroxide (1310-73-2)
Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

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.