SECTION 1 Identification

1.1. Product identifier

Product form : Mixture
Product name : MicroVue™ PYD EIA Kit
Product code : 8010

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Recommended use : For in vitro diagnostic use
Restrictions on use : Professional Use of Medical Devices

1.4. Supplier's details

Manufacturer
Ortho-Clinical Diagnostics, Inc.
2005 East State Street, Suite 100
Athens, OH, 45701
U.S.A.
T 1.800.874.1517 - F 1.740.592.9820
Contact Us | QuidelOrtho - techdocs.quidelortho.com

1.5. Emergency phone number

Emergency number : 1.866.519.4752

SECTION 2 Hazard Identification

2.1. Classification of the substance or mixture

GHS US classification

Components	GHS US classification
Substrate Buffer (10 mL)	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 2, H373
Stop Solution (15 mL)	Skin Irrit. 2, H315 Eye Irrit. 2, H319

2.2. Label elements

GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
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, forearms and face thoroughly after handling. P280 - Wear protective gloves, protective clothing, eye protection, face protection, and hearing protection. 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 or attention. P501 - Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.
Stop Solution (15 mL)		Warning	H315 - Causes skin irritation H319 - Causes serious eye irritation	P264 - Wash hands, forearms and face thoroughly after handling. P280 - Wear protective gloves, protective clothing, eye protection, face protection, and hearing protection. 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. P321 - Specific treatment (see supplemental first aid instruction on this label). P332+P313 - If skin irritation occurs: Get medical advice or attention. P337+P313 - If eye irritation persists: Get medical advice or attention. P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

Other hazards which do not result in classification : Contains Sodium Azide. Follow Universal Precautions when handling this component. This product contains material of human and/or animal origin.

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS #	%	GHS US classification
Substrate Buffer (10 mL)	diethanolamine	111-42-2	11.5	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Carc. 2, H351 STOT RE 2, H373 Aquatic Acute 2, H401
Stop Solution (15 mL)	sodium hydroxide	1310-73-2	1.5	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of hazard classes and H-statements : see section 16

SECTION 4 First aid measures

4.1. Description of necessary 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. Take off contaminated clothing. 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/doctor/physician if you feel unwell.

4.2. Most important symptoms/effects, acute and delayed

Symptoms/effects after skin contact : Irritation.

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

4.3. Indication of immediate medical attention and special treatment needed, if necessary

Other medical advice or treatment : 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

Hazardous decomposition products in case of fire : Toxic fumes may be released.

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

For non-emergency personnel

Emergency procedures : Ventilate spillage area. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin and eyes.

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".

Environmental precautions : Avoid release to the environment.

6.2. Methods and materials 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.

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. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin and eyes. Wear personal protective equipment.

Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including 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)	
USA - ACGIH - Occupational Exposure Limits	
ACGIH OEL C	2 mg/m³
USA - OSHA - Occupational Exposure Limits	
Local name	Sodium hydroxide

sodium hydroxide (1310-73-2)	
OSHA PEL TWA	2 mg/m³
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1
USA - Cal/OSHA - Occupational Exposure Limits	
Local name	Sodium hydroxide; caustic soda
Cal/OSHA PEL (OEL TWA)	2 mg/m³
Cal/OSHA C	2 mg/m³
Regulatory reference	California Division of Occupational Safety and Health (Cal/OSHA) - Permissible Exposure Limit for Chemical Contaminants (Table AC-1)
USA - IDLH - Occupational Exposure Limits	
IDLH	10 mg/m³
USA - NIOSH - Occupational Exposure Limits	
Local name	Sodium hydroxide
NIOSH REL C	2 mg/m³
US-NIOSH chemical category	SK: DIR(COR) Apr 2011
Regulatory reference (US-NIOSH)	OSHA Annotated Table Z-1 (NIOSH Pocket Guide to Chemical Hazards (NPG))

diethanolamine (111-42-2)	
USA - ACGIH - Occupational Exposure Limits	
ACGIH OEL TWA	1 mg/m³ (Inhalable fraction and vapor)

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, such as personal protective equipment

Materials for protective clothing:
Lab coat

Hand protection:				
Wear protective gloves. Wash your hands				
Type	**Material**	**Permeation**	**Thickness (mm)**	**Penetration**
Medical Grade Disposable Gloves (powder-free) recommended	Nitrile rubber (NBR)	2 (> 30 minutes)	4	2 (< 1.5)

Eye protection:
Safety glasses

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. 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
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
Viscosity, kinematic	:	No data available
Explosion limits	:	No data available
Particle characteristics	:	No data available

9.2. Data relevant with regard to physical hazard classes (supplemental)

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

sodium hydroxide (1310-73-2)	
LD50 oral rat	325 mg/kg (Source: OECD_SIDS)
LD50 dermal rabbit	1350 mg/kg (Source: NLM_HSDB)
ATE US (oral)	325 mg/kg body weight
ATE US (dermal)	1350 mg/kg body weight

diethanolamine (111-42-2)	
LD50 oral rat	1600 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral, 14 day(s))
ATE US (oral)	1600 mg/kg body weight

Skin corrosion/irritation : Causes skin irritation.
pH: Stop Solution, pH <13

sodium hydroxide (1310-73-2)	
pH	14 (5 %)

diethanolamine (111-42-2)	
pH	11 (53 g/l)

Serious eye damage/irritation : Causes serious eye damage.
pH: Stop Solution, pH <13

sodium hydroxide (1310-73-2)	
pH	14 (5 %)

diethanolamine (111-42-2)	
pH	11 (53 g/l)

Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified

Carcinogenicity : Suspected of causing cancer.

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

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

diethanolamine (111-42-2)	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

MicroVue PYD EIA Kit	
Viscosity, kinematic	No data available

sodium hydroxide (1310-73-2)	
Viscosity, kinematic	No data available in the literature
diethanolamine (111-42-2)	
Viscosity, kinematic	357.967 mm²/s

Symptoms/effects after skin contact : Irritation.

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

SECTION 12 Ecological information

12.1. Ecotoxicity

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

Hazardous to the aquatic environment, short–term (acute) : Harmful to aquatic life.

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

sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	189 mg/l (48 h, Leuciscus idus, Fresh water, Experimental value)
EC50 - Crustacea [1]	40 mg/l (48 h, Ceriodaphnia sp., Experimental value, Locomotor effect)
diethanolamine (111-42-2)	
LC50 - Fish [1]	460 mg/l (96 h, Oncorhynchus mykiss, Static system, Fresh water, Experimental value, Nominal concentration)
EC50 - Crustacea [1]	30.1 – 89.9 mg/l (ASTM E729-80, 48 h, Ceriodaphnia dubia, Static system, Fresh water, Experimental value, Locomotor effect)
ErC50 algae	9.5 mg/l (EPA 600/9-78-018, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Nominal concentration)

12.2. Persistence and degradability

MicroVue PYD EIA Kit	
Persistence and degradability	Rapidly degradable

sodium hydroxide (1310-73-2)	
Persistence and degradability	Biodegradability: not applicable.
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

12.3. Bioaccumulative potential

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

diethanolamine (111-42-2)	
BCF - Fish [1]	3.162 l/kg (BCFBAF v3.01, Estimated value, Fresh weight)
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)	
Surface tension	No data available in the literature
Ecology - soil	No (test)data on mobility of the substance available.

diethanolamine (111-42-2)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.98 – 1 (log Koc, Calculated value)
Ecology - soil	Highly mobile in soil.

12.5. Other adverse effects

Fluorinated greenhouse gases : No

SECTION 13 Disposal considerations

Regional waste regulation : 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.
Ecological waste information	:	Avoid release to the environment.

SECTION 14 Transport information

In accordance with DOT / IMDG / IATA

14.1. UN number

Not regulated for transport

14.2. UN Proper Shipping Name

Proper Shipping Name (DOT)	:	Not regulated
Proper Shipping Name (IMDG)	:	Not regulated
Proper Shipping Name (IATA)	:	Not regulated

14.3. Transport hazard class(es)

DOT

Transport hazard class(es) (DOT) : Not regulated

IMDG

Transport hazard class(es) (IMDG) : Not regulated

IATA

Transport hazard class(es) (IATA) : Not regulated

14.4. Packing group

Packing group (DOT)	:	Not regulated
Packing group (IMDG)	:	Not regulated
Packing group (IATA)	:	Not regulated

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Transport in bulk

Not applicable

14.7. Special precautions for user

DOT

Not regulated

IMDG

Not regulated

IATA

Not regulated

SECTION 15 Regulatory information

15.1. Federal regulations

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:		
diethanolamine	CAS No 111-42-2	11.5%

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. 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
Revision date : 3/24/2025
Issue date : 3/29/2022
Other information : Please review product insert prior to using this product.

Full text of hazard classes and H-statements	
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage

Full text of hazard classes and H-statements	
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life
H402	Harmful to aquatic life

SDS US Quidel Kit

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.