

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Issue date: 2/9/2022 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture

Product name : MicroVue Serum PYD EIA Kit

Product code : 8019

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec : For research use only

1.2.2. Uses advised against

Restrictions on use : Restricted to professional users

1.3. Details of the supplier of the safety data sheet

Manufacturer

Quidel Corporation 2005 East State Street, Suite 100 45701 Athens - 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: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Components	CLP classification
Reagent 1 (6 mL)	Skin Sens. 1, H317
Stop Solution (15 mL)	Skin Irrit. 2, H315 Eye Irrit. 2, H319
Substrate Buffer (30 mL)	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 2, H373

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Reagent 1 (6 mL)	(!)	Warning	H317 - May cause an allergic skin reaction.	P280 - Wear gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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Stop Solution (15 mL)	Warning	H315 - Causes skin irritation.	P264 - Wash hands thoroughly after handling.
		H319 - Causes serious eye	P280 - Wear gloves, safety glasses, and lab coat.
	\	irritation.	P302+P352 - IF ON SKIN: Wash with plenty of 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.
		P362+P364 - Take off contaminated clothing and wash it before reuse.	
Substrate Buffer (30 mL)	Danger	H315 - Causes skin irritation.	P260 - Do not breathe mist, spray.
damage. H373 - May cause damage		P264 - Wash hands thoroughly after handling.	
		P280 - Wear gloves, safety glasses, and lab coat.	
	H373 - May cause damage to organs through prolonged or	P302+P352 - IF ON SKIN: Wash with plenty of soap and water.	
	repeated exposure.	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 to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS No EC-No.	%	CLP classification
Substrate Buffer (30 mL)	Diethanolamine	111-42-2 -	10 – 15	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 2, H373
Stop Solution (15 mL)	sodium hydroxide	1310-73-2 -	1-5	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Reagent 1 (6 mL)	Mixture for ProClin 300: 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 -	0.05	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

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
sodium hydroxide	(EC-No.) 215-185-5 (EC Index-No.) 011-002-00-6	(0.5 ≤C < 2) Eye Irrit. 2, H319 (0.5 ≤C < 2) Skin Irrit. 2, H315 (2 ≤C < 5) Skin Corr. 1B, H314 (5 ≤C < 100) Skin Corr. 1A, H314

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mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. (CAS No) 55965-84-9 (0.0015 ≤C < 100) Skin Sens. 1, H317 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-(EC Index-No.) 613-167-00-5 (0.06 ≤C < 0.6) Eye Irrit. 2, H319 239-6] (3:1) (0.06 ≤C < 0.6) Skin Irrit. 2, H315 (0.6 ≤C < 100) Skin Corr. 1B, H314

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of 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. 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, both acute and delayed

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

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

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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. Do not breathe mist, spray. 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

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

: Take up liquid spill into absorbent material. Methods for cleaning up

Other information : Dispose of materials or solid residues at an authorized site.

6.4. 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. Do not breathe

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.

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

sodium hydroxide (1310-73-2)		
Belgium	OEL TWA	2 mg/m³
France	VME (OEL TWA)	2 mg/m³
United Kingdom	WEL STEL (OEL STEL)	2 mg/m³
USA - ACGIH	ACGIH OEL C	2 mg/m³
USA - OSHA	Local name	Sodium hydroxide
USA - OSHA	OSHA PEL TWA [1]	2 mg/m³

diethanolamine (111-42-2)		
Belgium	OEL TWA	2 mg/m³
Belgium	OEL TWA [ppm]	0.46 ppm
France	VME (OEL TWA)	15 mg/m³
France	VME (OEL TWA) [ppm]	3 ppm
USA - ACGIH	ACGIH OEL TWA	1 mg/m³ (Inhalable fraction and vapor)

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

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):









Environmental exposure controls:

Avoid release to the environment.

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

Colour : No data available

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Odour : No data available
Odour threshold : No data available

pH : Reagent 1, pH 2.5

: Substrate Buffer, pH 9.9: Stop Solution pH, < 13

: Not applicable

Relative evaporation rate (butylacetate=1) : No data available
Melting point : Not applicable
Freezing point : No data available

Boiling point : No data available
Flash point : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Vapour pressure : No data available
Relative vapour 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
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

Flammability (solid, gas)

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

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)

84-9)	-9)		
LD50 oral rat	53 mg/kg (Rat, Literature study)		
LD50 dermal	200 – 1000 mg/kg bodyweight (Literature study)		

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diethanolamine (111-42-2)	
LD50 oral rat	620 mg/kg (Rat)
LD50 dermal rabbit	7640 mg/kg (Rabbit)
Skin corrosion/irritation :	Causes skin irritation.
Serious eye damage/irritation	Causes serious eye damage.
Respiratory or skin sensitisation	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	May cause damage to organs through prolonged or repeated exposure.

SECTION 12: Ecological information

12.1. Toxicity

Aspiration hazard

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects

in the environment.

Hazardous to the aquatic environment, short-term

: Not classified

: Not classified

Hazardous to the aquatic environment, long-term

(chronic)

: 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)	
LC50 - Fish [1]	0.28 mg/l (96 h, Lepomis macrochirus, Literature)
EC50 - Crustacea [1]	0.16 mg/l (48 h, Daphnia magna, Literature)
EC50 72h - Algae [1]	0.018 mg/l (Pseudokirchneriella subcapitata, Literature)

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)

diethanolamine (111-42-2)	
LC50 - Fish [1]	1664 mg/l (96 h, Pimephales promelas, Static system)
EC50 - Crustacea [1]	55 mg/l (48 h, Daphnia magna)
EC50 72h - Algae [1]	75 mg/l (Scenedesmus subspicatus)

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.

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)

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ThOD	Not applicable (inorganic)
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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
BOD (% of ThOD)	0.1

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) Not established. Bioaccumulative potential

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

diethanolamine (111-42-2)		
	Partition coefficient n-octanol/water (Log Pow)	-2.18 – -1.43 (Experimental value)
	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.

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

12.5. Results of PBT and vPvB assessment

Component	
diethanolamine (111-42-2)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
sodium hydroxide (1310-73-2)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment 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

In accordance with ADR / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR) : Not regulated UN-No. (IMDG) : Not regulated

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UN-No. (IATA) : Not regulated UN-No. (ADN) : Not regulated

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated
Proper Shipping Name (ADN) : Not regulated

14.3. Transport hazard class(es)

ADR

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

IMDG

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

IATA

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

ADN

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

14.4. Packing group

Packing group (ADR) : Not regulated
Packing group (IMDG) : Not regulated
Packing group (IATA) : Not regulated
Packing group (ADN) : Not regulated

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Regulatory reference : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)

Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

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Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed SZW-lijst van mutagene stoffen : None of the components are listed SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Pregnant/breastfeeding women working with the product must not be in direct contact with the

product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

1 12 12
Indication of changes:
mulcation of changes.

New EU SDS template.

tew to 353 template.		
Abbreviations and acronyms:		
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
ATE	Acute Toxicity Estimate	
BLV	Biological limit value	
CAS No	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
EN	European Standard	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LC50	Median lethal concentration	
LD50	Median lethal dose	
LOAEL	Lowest Observed Adverse Effect Level	
NOAEC	No-Observed Adverse Effect Concentration	
NOAEL	No-Observed Adverse Effect Level	
NOEC	No-Observed Effect Concentration	
OEL	Occupational Exposure Limit	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Other information : Please review product insert prior to using this product.

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Full text of H- and EUH-statements:	Full text of H- and EUH-statements:		
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2		
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3		
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3		
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3		
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4		
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1		
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1		
Eye Dam. 1	Serious eye damage/eye irritation, Category 1		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2		
H290	May be corrosive to metals.		
H300	Fatal if swallowed.		
H301	Toxic if swallowed.		
H302	Harmful if swallowed.		
H311	Toxic in contact with skin.		
H314	Causes severe skin burns and eye damage.		
H315	Causes skin irritation.		
H317	May cause an allergic skin reaction.		
H318	Causes serious eye damage.		
H319	Causes serious eye irritation.		
H331	Toxic if inhaled.		
H373	May cause damage to organs through prolonged or repeated exposure.		
H400	Very toxic to aquatic life.		
H410	Very toxic to aquatic life with long lasting effects.		
Met. Corr. 1	Corrosive to metals, Category 1		
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A		
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B		
Skin Irrit. 2	Skin corrosion/irritation, Category 2		
Skin Sens. 1	Skin sensitisation, Category 1		
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2		

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.

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