

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

1.1. Product identifier

Product form : Mixture
Product name : MicroVue Bone Klotho Assay
Product code : 8050
Product group : Kit

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. For in vitro diagnostic use.

1.2.2. Uses advised against

Restrictions on use : Restricted to professional users. Professional Use of Medical Devices.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Diagnostic Hybrids, Inc. a subsidiary of Quidel Corporation
2005 East State Street, Suite 100
45701 Athens - USA
T 1.800.874.1517 - F 1.740.592.9820
gehs@quidelortho.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
MicroVue Bone Klotho Standards and Controls	Skin Sens. 1, H317
Stop Solution (12 mL)	Met. Corr. 1, H290 Skin Corr. 1, H314 Eye Dam. 1, H318
20X Wash Solution Concentrate (50 mL)	Met. Corr. 1, H290 Skin Sens. 1, H317
Hydrating Reagent (25 mL)	Skin Sens. 1, H317
TMB Substrate (12 mL)	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 1B, H360 STOT SE 3, H335






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


Adverse physicochemical, human health and environmental effects

May be corrosive to metals. May damage fertility or the unborn child. May cause respiratory irritation. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
MicroVue Bone Klotho Standards and Controls		Warning	H317 - May cause an allergic skin reaction.	P261 - Avoid breathing mist, spray. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves and safety glasses. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P321 - Specific treatment: Seek medical attention if ill effect develops P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.	No additional information available
Stop Solution (12 mL)		Danger	H290 - May be corrosive to metals. H314 - Causes severe skin burns and eye damage.	P261 - Avoid breathing 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	No additional information available
20X Wash Solution Concentrate (50 mL)	 	Warning	H290 - May be corrosive to metals. H317 - May cause an allergic skin reaction.	P280 - Wear gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention	No additional information available
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 with plenty of water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.	No additional information available

TMB Substrate (12 mL)		Danger	<p>H225 - Highly flammable liquid and vapour. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. H360 - May damage fertility or the unborn child.</p>	<p>P264 - Wash hands, forearms and face thoroughly after handling. P280 - Wear gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of water. 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. 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 to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.</p>	No additional information available
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2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ 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
TMB Substrate (12 mL)	acetone	67-64-1 -	1 – 10	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
TMB Substrate (12 mL)	1-methyl-2-pyrrolidone	872-50-4 -	1 – 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 1B, H360D STOT SE 3, H335
TMB Substrate (12 mL)	1-ethylpyrrolidin-2-one	2687-91-4 -	1 – 5	Repr. 1B, H360D STOT RE 2, H373
Hydrating Reagent (25 mL)	ProClin® 300	55965-84-9 -	0.035	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 STOT RE 1, H372 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 2, H411 (M=100)
Specimen Diluent	Methylisothiazolone	26172-54-3 -	0.02	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1A, H314 Skin Sens. 1A, H317 Aquatic Chronic 1, H410

20X Wash Solution Concentrate (50 mL)	ProClin® 300	55965-84-9 -	0.037	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 STOT RE 1, H372 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 2, H411 (M=100)
20X Wash Solution Concentrate (50 mL)	disodium hydrogenorthophosphate	7558-79-4 -	2.53	Acute Tox. 3 (Inhalation:dust,mist), H331
Stop Solution (12 mL)	hydrochloric acid	7647-01-0 -	4	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335
MicroVue Klotho Standards and Controls	ProClin® 300	55965-84-9 -	0.035	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 STOT RE 1, H372 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 2, H411 (M=100)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
1-methyl-2-pyrrolidone	(CAS No) 872-50-4 (EC-No.) 212-828-1 (EC Index-No.) 606-021-00-7	(10 ≤ C ≤ 100) STOT SE 3, H335
hydrochloric acid	(CAS No) 7647-01-0 (EC-No.) 231-595-7 (EC Index-No.) 017-002-01-X	(10 ≤ C < 25) Skin Irrit. 2, H315 (10 ≤ C < 25) Eye Irrit. 2, H319 (10 ≤ C ≤ 100) STOT SE 3, H335 (25 ≤ C ≤ 100) Skin Corr. 1B, H314
ProClin® 300	(CAS No) 55965-84-9 (EC Index-No.) 613-167-00-5	(0.0015 ≤ C ≤ 100) Skin Sens. 1A, H317 (0.06 ≤ C < 0.6) Eye Irrit. 2, H319 (0.06 ≤ C < 0.6) Skin Irrit. 2, H315 (0.6 ≤ C ≤ 100) Eye Dam. 1, H318 (0.6 ≤ C ≤ 100) Skin Corr. 1C, 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	: IF exposed or concerned: Get medical advice/attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
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. 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, both acute and delayed

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Eye irritation.

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 : Only qualified personnel equipped with suitable protective equipment may intervene. Avoid breathing dust/fume/gas/mist/vapours/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

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.

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 : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

Hygiene measures : Separate working clothes from town clothes. Launder separately. 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 corrosive resistant container with a resistant inner liner. Keep only in original container. Store locked up. Store in a well-ventilated place. Keep container tightly closed. Keep cool.

Incompatible materials : Metals.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

hydrochloric acid (7647-01-0)		
USA - OSHA	Local name	Hydrogen chloride
USA - OSHA	OSHA PEL C	7 mg/m ³
USA - OSHA	OSHA PEL C [ppm]	5 ppm

1-ethylpyrrolidin-2-one (2687-91-4)		
USA - ACGIH	BEI	Parameter: 5-hydroxy-N-ethyl-2-pyrrolidone (5-HNEP) (without hydrolysis) - Medium: urine - Sampling time: End of shift - Notations: Nq

acetone (67-64-1)		
EU	IOEL TWA	1210 mg/m ³
EU	IOEL TWA [ppm]	500 ppm
Belgium	OEL TWA	594 mg/m ³
Belgium	OEL TWA [ppm]	246 ppm
Belgium	OEL STEL	1187 mg/m ³
Belgium	OEL STEL [ppm]	492 ppm
France	VME (OEL TWA)	1210 mg/m ³
France	VME (OEL TWA) [ppm]	500 ppm
France	VLE (OEL C/STEL)	2420 mg/m ³
France	VLE (OEL C/STEL) [ppm]	1000 ppm
Netherlands	TGG-8u (OEL TWA)	1210 mg/m ³
Netherlands	TGG-8u (OEL TWA) [ppm]	500 ppm
Netherlands	TGG-15min (OEL STEL)	2420 mg/m ³
Netherlands	TGG-15min (OEL STEL) [ppm]	1002 ppm
United Kingdom	WEL TWA (OEL TWA) [1]	1210 mg/m ³
United Kingdom	WEL TWA (OEL TWA) [2]	500 ppm
United Kingdom	WEL STEL (OEL STEL)	3620 mg/m ³
United Kingdom	WEL STEL (OEL STEL) [ppm]	1500 ppm
USA - ACGIH	ACGIH OEL TWA [ppm]	250 ppm
USA - ACGIH	ACGIH OEL STEL [ppm]	500 ppm
USA - ACGIH	BEI	25 mg/l Parameter: Acetone - Medium: urine - Sampling time: End of shift - Notations: Ns
USA - OSHA	Local name	Acetone
USA - OSHA	OSHA PEL TWA [1]	2400 mg/m ³
USA - OSHA	OSHA PEL TWA [2]	1000 ppm

1-methyl-2-pyrrolidone (872-50-4)		
EU	IOEL TWA	40 mg/m ³
EU	IOEL TWA [ppm]	10 ppm
EU	IOEL STEL	80 mg/m ³
EU	IOEL STEL [ppm]	20 ppm
Belgium	OEL TWA	40 mg/m ³
Belgium	OEL TWA [ppm]	10 ppm
Belgium	OEL STEL	80 mg/m ³
Belgium	OEL STEL [ppm]	20 ppm
France	VME (OEL TWA)	40 mg/m ³
France	VME (OEL TWA) [ppm]	10 ppm
France	VLE (OEL C/STEL)	80 mg/m ³
France	VLE (OEL C/STEL) [ppm]	20 ppm

1-methyl-2-pyrrolidone (872-50-4)		
Netherlands	TGG-8u (OEL TWA)	40 mg/m ³
Netherlands	TGG-8u (OEL TWA) [ppm]	10 ppm
Netherlands	TGG-15min (OEL STEL)	80 mg/m ³
Netherlands	TGG-15min (OEL STEL) [ppm]	20 ppm
United Kingdom	WEL TWA (OEL TWA) [1]	40 mg/m ³
United Kingdom	WEL TWA (OEL TWA) [2]	10 ppm
United Kingdom	WEL STEL (OEL STEL)	80 mg/m ³
United Kingdom	WEL STEL (OEL STEL) [ppm]	20 ppm
USA - ACGIH	BEI	100 mg/l Parameter: 5-Hydroxy-N-methyl-2-pyrrolidone - Medium: urine - Sampling time: End of shift

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

Lab coat

Hand protection:

Wear protective gloves. Wash your hands

Eye protection:

Safety glasses

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

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
Appearance	: EIA Kit
Colour	: Clear
Odour	: Mild
Odour threshold	: No data available
pH	: ≤ 1 Stop Solution
pH	: 5.8 – 6.6 % TMB Substrate, 20X Wash Solution Concentrate
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
Flammability	: Not applicable
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

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

metals.

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50 oral rat	66 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Calculated by reference to active substance, Oral, 14 day(s))
LD50 dermal rat	> 141 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s))
LC50 Inhalation - Rat	0.17 mg/l air (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Calculated by reference to active substance, Inhalation (dust), 14 day(s))

disodium hydrogenorthophosphate (7558-79-4)	
LD50 oral rat	> 2000 mg/kg bodyweight (OECD 420: Acute Oral toxicity – Acute Toxic Class Method, Rat, Female, Experimental value, Oral, 14 day(s))
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s))
LC50 Inhalation - Rat	> 0.83 mg/l (EPA OPP 81-3: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s))

Methylisothiazolone (26172-54-3)	
LD50 oral rat	175 mg/kg
LD50 dermal rat	246 mg/kg
LC50 Inhalation - Rat	0.11 mg/l 4 hr

1-ethylpyrrolidin-2-one (2687-91-4)	
LD50 oral rat	3200 mg/kg bodyweight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral)
LD50 dermal rat	> 2000 mg/kg bodyweight (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))

acetone (67-64-1)	
LD50 oral rat	5800 mg/kg (Rat, Female, Experimental value, Oral, 14 day(s))
LD50 dermal rabbit	> 15800 mg/kg bodyweight (24 h, Rabbit, Male, Experimental value, Dermal, 14 day(s))
LC50 Inhalation - Rat	132 mg/l (3 h, Rat, Male, Experimental value, Inhalation (vapours))

1-methyl-2-pyrrolidone (872-50-4)	
LD50 oral rat	4150 mg/kg bodyweight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral, 14 day(s))
LD50 dermal rat	> 5000 mg/kg bodyweight (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))

Skin corrosion/irritation	: Causes skin irritation. pH: ≤ 1 Stop Solution
Serious eye damage/irritation	: Causes serious eye irritation. pH: ≤ 1 Stop Solution
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

1-methyl-2-pyrrolidone (872-50-4)	
NOAEL (chronic, oral, animal/male, 2 years)	≈ 89 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: OECD Guideline 451 (Carcinogenicity Studies), Guideline: EU Method B.32 (Carcinogenicity Test), Guideline: EPA OTS 798.3300 (Carcinogenicity), Remarks on results: other:
NOAEL (chronic, oral, animal/female, 2 years)	≈ 221 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: OECD Guideline 451 (Carcinogenicity Studies), Guideline: EU Method B.32 (Carcinogenicity Test), Guideline: EPA OTS 798.3300 (Carcinogenicity), Remarks on results: other:

Reproductive toxicity	: May damage fertility or the unborn child.
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acetone (67-64-1)	
LOAEL (animal/female, F0/P)	11298 mg/kg bodyweight Animal: mouse, Animal sex: female
NOAEL (animal/male, F0/P)	900 mg/kg bodyweight Animal: rat, Animal sex: male

1-methyl-2-pyrrolidone (872-50-4)	
LOAEL (animal/female, F0/P)	500 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study)
NOAEL (animal/male, F0/P)	≥ 500 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study)
NOAEL (animal/female, F0/P)	350 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 416 (Two-Generation Reproduction Toxicity Study)

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LOAEL (dermal, rat/rabbit, 90 days)	0.525 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: EPA OPP 82-3 (Subchronic Dermal Toxicity 90 Days)

disodium hydrogenorthophosphate (7558-79-4)	
NOAEL (oral, rat, 90 days)	1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)

1-ethylpyrrolidin-2-one (2687-91-4)	
LOAEC (inhalation, rat, vapour, 90 days)	0.2 mg/l air Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Guideline: EU Method B.29 (Sub-Chronic Inhalation Toxicity:90-Day Study), Guideline: EPA OPPTS 870.3465 (90-Day Inhalation Toxicity)
NOAEL (oral, rat, 90 days)	100 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents)
NOAEC (inhalation, rat, vapour, 90 days)	0.06 mg/l air Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Guideline: EU Method B.29 (Sub-Chronic Inhalation Toxicity:90-Day Study), Guideline: EPA OPPTS 870.3465 (90-Day Inhalation Toxicity)
NOAEC (inhalation, rat, dust/mist/fume, 90 days)	0.08 mg/l air Animal: rat, Guideline: OECD Guideline 412 (Subacute Inhalation Toxicity: 28-Day Study), Guideline: EU Method B.8 (Subacute Inhalation Toxicity: 28-Day Study)

1-methyl-2-pyrrolidone (872-50-4)	
LOAEL (dermal, rat/rabbit, 90 days)	1653 mg/kg bodyweight Animal: rabbit, Animal sex: male, Guideline: OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study)
NOAEL (dermal, rat/rabbit, 90 days)	826 mg/kg bodyweight Animal: rabbit, Animal sex: male, Guideline: OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study)

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

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 (acute) : Not classified

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LC50 - Fish [1]	0.19 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
LC50 - Fish [2]	0.28 mg/l Test organisms (species): Lepomis macrochirus
EC50 - Crustacea [1]	0.007 mg/l (48 h, Acartia tonsa, Salt water, Experimental value, GLP)
NOEC (chronic)	0.1 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	0.098 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '28 d'

disodium hydrogenorthophosphate (7558-79-4)	
LC50 - Fish [1]	> 100 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value, GLP)
EC50 - Crustacea [1]	> 100 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)
ErC50 algae	> 100 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, GLP)

Methylisothiazolone (26172-54-3)	
LC50 - Fish [1]	4.77 mg/l Oncorhynchus mykiss - 96 hr
LC50 - Other aquatic organisms [1]	2.33 mg/l Daphnia magna (Water Flea) - 48 hr
EC50 - Crustacea [1]	2.33 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	0.289 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

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)
EC50 72h - Algae [1]	> 101 mg/l (OECD 201: Alga, Growth Inhibition Test, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Growth rate)
LOEC (chronic)	25 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	12.5 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

acetone (67-64-1)	
LC50 - Fish [1]	6210 – 8120 mg/l (Equivalent or similar to OECD 203, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Measured concentration)
LOEC (chronic)	> 79 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	≥ 79 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

1-methyl-2-pyrrolidone (872-50-4)	
LC50 - Fish [1]	> 500 mg/l (96 h, Oncorhynchus mykiss, Static system, Fresh water, Experimental value, Lethal)
EC50 - Crustacea [1]	> 1000 mg/l (DIN 38412-11, 24 h, Daphnia magna, Static system, Fresh water, Experimental value, Lethal)
EC50 72h - Algae [1]	600.5 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)
EC50 72h - Algae [2]	672.8 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)
ErC50 algae	600.5 mg/l (DIN 38412-9, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Nominal concentration)
LOEC (chronic)	25 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	12.5 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

12.2. Persistence and degradability

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Persistence and degradability	Not readily biodegradable in water.
Biochemical oxygen demand (BOD)	Not applicable.
Chemical oxygen demand (COD)	Not applicable.
ThOD	Not applicable.
BOD (% of ThOD)	Not applicable.

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

disodium hydrogenorthophosphate (7558-79-4)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

1-ethylpyrrolidin-2-one (2687-91-4)	
Persistence and degradability	Readily biodegradable in water.

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

1-methyl-2-pyrrolidone (872-50-4)	
Persistence and degradability	Readily 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

12.3. Bioaccumulative potential

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
BCF - Fish [1]	41 – 54 (OECD 305: Bioconcentration: Flow-Through Fish Test, 28 day(s), Lepomis macrochirus, Flow-through system, Fresh water, Experimental value, Fresh weight)
Partition coefficient n-octanol/water (Log Pow)	0.75 (24 °C)
Bioaccumulative potential	Not established.

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

disodium hydrogenorthophosphate (7558-79-4)	
Bioaccumulative potential	Not bioaccumulative.

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.

acetone (67-64-1)	
BCF - Fish [1]	0.69 (Pisces, Literature study)
Partition coefficient n-octanol/water (Log Pow)	-0.23 (Test data)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

1-methyl-2-pyrrolidone (872-50-4)	
Partition coefficient n-octanol/water (Log Pow)	-0.46 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 25 °C)
Bioaccumulative potential	Not bioaccumulative.

12.4. Mobility in soil

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Surface tension	No data available in the literature
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.81 – 1 (log Koc, Calculated value)
Ecology - soil	Highly mobile in soil.

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

disodium hydrogenorthophosphate (7558-79-4)	
Ecology - soil	No (test)data on mobility of the substance available.

1-ethylpyrrolidin-2-one (2687-91-4)	
Surface tension	69 mN/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.

acetone (67-64-1)	
Surface tension	23.3 mN/m (20 °C)
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.374 – 0.988 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Highly mobile in soil.

1-methyl-2-pyrrolidone (872-50-4)	
Surface tension	No data available in the literature
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.87 (log Koc, SRC PCKOCWIN v2.0, QSAR)
Ecology - soil	Highly mobile in soil.

12.5. Results of PBT and vPvB assessment

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	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
hydrochloric acid (7647-01-0)	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
disodium hydrogenorthophosphate (7558-79-4)	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
1-ethylpyrrolidin-2-one (2687-91-4)	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
acetone (67-64-1)	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
1-methyl-2-pyrrolidone (872-50-4)	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

14.1. UN number

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

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

14.4. Packing group

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

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 substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains substance(s) listed on the REACH Candidate List in concentrations $\geq 0.1\%$ or SCL: 1-Methyl-2-pyrrolidone (NMP) (EC 212-828-1, CAS 872-50-4)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

15.1.2. National regulations

Germany

Regulatory reference	: WGK 3, Highly 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)

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	: 1-ethylpyrrolidin-2-one, 1-methyl-2-pyrrolidone 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
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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:	
Regulatory Review. New EU SDS 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.

Full text of H- and EUH-statements:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
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.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H360	May damage fertility or the unborn child.
H360D	May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
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.

H411	Toxic to aquatic life with long lasting effects.
Met. Corr. 1	Corrosive to metals, Category 1
Repr. 1B	Reproductive toxicity, Category 1B
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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.