

SECTION 1: Identification of the substance/mixture and of the company/undertaking
1.1. Product identifier

Product form	: Mixture
Product name	: MicroVue CIC-Raji Cell Replacement EIA Kit
Product code	: A002
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 in vitro diagnostic use
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1.2.2. Uses advised against

Restrictions on use	: Professional Use of Medical Devices
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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
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SECTION 2: Hazards identification
2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP]




Components	CLP classification
Specimen Diluent (50 mL)	Skin Sens. 1, H317
CIC-Raji Confirmation Diluent (12 mL)	Skin Sens. 1, H317
20X Wash Solution Concentrate (50 mL)	Skin Sens. 1, H317
Stop Solution (6 mL)	Skin Corr. 1A, H314 Eye Dam. 1, H318
Substrate Diluent (25 mL)	Skin Irrit. 2, H315 Eye Irrit. 2, H319

Adverse physicochemical, human health and environmental effects

May be corrosive to metals. 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
Specimen Diluent (50 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 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.
CIC-Raji Confirmation Diluent (12 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 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.

20X Wash Solution Concentrate (50 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 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.
Stop Solution (6 mL)		Danger	H314 - Causes severe skin burns and eye damage.	P260 - Do not breathe the mist, spray. P264 - Wash hands thoroughly after handling. P280 - Wear gloves, safety glasses, and lab coat. P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with 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. P321 - Specific treatment (see supplemental first aid instruction on this label). P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Substrate Diluent (25 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 with plenty of 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 to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS No EC-No.	%	CLP classification
1. Specimen Diluent (50 mL) 2. CIC-Raji Confirmation Diluent (12 mL) 3. 20X Wash Solution Concentrate (50 mL)	<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
Substrate Diluent (25 mL)	citric acid, monohydrate	5949-29-1 -	1-5	Skin Corr. 1A, H314 Eye Dam. 1, H318
Stop Solution (6 mL)	oxalic acid, dihydrate	6153-56-6 -	1-5	Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
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)	(CAS No) 55965-84-9 (EC Index-No.) 613-167-00-5	(0.0015 ≤ C < 100) Skin Sens. 1, H317 (0.06 ≤ C < 0.6) Eye Irrit. 2, H319 (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 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.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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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.
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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. Avoid breathing mist, spray.
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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".
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6.2. 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.

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. 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

Storage conditions	: Store in corrosive resistant container with a resistant inner liner. Keep only in original container. Store in a well-ventilated place. 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

oxalic acid, dihydrate (6153-56-6)		
EU	IOEL TWA	1 mg/m ³
Belgium	OEL TWA	1 mg/m ³ 1 mg/m ³
Belgium	OEL STEL	2 mg/m ³ 2 mg/m ³
France	VME (OEL TWA)	1 mg/m ³
Netherlands	TGG-8u (OEL TWA)	1 mg/m ³
United Kingdom	WEL TWA (OEL TWA) [1]	1 mg/m ³
United Kingdom	WEL STEL (OEL STEL)	2 mg/m ³
USA - ACGIH	ACGIH OEL TWA	1 mg/m ³
USA - ACGIH	ACGIH OEL STEL	2 mg/m ³

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
Odour	: No data available
Odour threshold	: No data available
pH	: Stop Solution, pH <2
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 (solid, gas)	: 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

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)

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

citric acid, monohydrate (5949-29-1)	
LD50 oral	5400 mg/kg bodyweight (Equivalent or similar to OECD 401, Mouse, Male/female, Experimental value)
LD50 dermal rat	> 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male/female, Experimental value)

oxalic acid, dihydrate (6153-56-6)	
LD50 oral rat	475 mg/kg bodyweight (Rat, Male, Experimental value, Anhydrous form, Oral)
LD50 dermal rabbit	20000 mg/kg bodyweight (Rabbit, Experimental value, Anhydrous form, Dermal)

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	: Not classified
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

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)

citric acid, monohydrate (5949-29-1)	
LC50 - Fish [1]	440 – 760 mg/l (Equivalent or similar to OECD 203, 48 h, Leuciscus idus, Static system, Fresh water, Experimental value)
EC50 - Crustacea [1]	1535 mg/l (Other, 24 h, Daphnia magna, Static system, Fresh water, Experimental value)

oxalic acid, dihydrate (6153-56-6)	
LC50 - Fish [1]	160 mg/l (48 h, Leuciscus idus, Static system, Fresh water, Experimental value, Anhydrous form)
LC50 - Other aquatic organisms [1]	5330 mg/l (96 h, Xenopus laevis, Fresh water, Experimental value, Anhydrous form)
EC50 - Crustacea [1]	162.2 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Fresh water, Experimental value, Anhydrous form)

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.
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citric acid, monohydrate (5949-29-1)	
Persistence and degradability	Biodegradable in the soil. Readily biodegradable in water.
Biochemical oxygen demand (BOD)	0.481 g O ₂ /g substance
Chemical oxygen demand (COD)	0.665 g O ₂ /g substance

oxalic acid, dihydrate (6153-56-6)	
Persistence and degradability	Biodegradable in the soil. Readily biodegradable in water. Readily biodegradable in water in anaerobic conditions.

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)	
Bioaccumulative potential	Not established.

citric acid, monohydrate (5949-29-1)	
Partition coefficient n-octanol/water (Log Pow)	-1.8 – -1.55 (Anhydrous form, Experimental value)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

oxalic acid, dihydrate (6153-56-6)	
Partition coefficient n-octanol/water (Log Pow)	-1.7 (Anhydrous form, Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 23 °C)
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.

citric acid, monohydrate (5949-29-1)	
Ecology - soil	No (test)data on mobility of the substance available.

oxalic acid, dihydrate (6153-56-6)	
Surface tension	70.1 N/m (25 °C, 0.015 mol/l)
Ecology - soil	No (test)data on mobility of the substance available.

12.5. Results of PBT and vPvB assessment

Component	
oxalic acid, dihydrate (6153-56-6)	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
citric acid, monohydrate (5949-29-1)	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

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
 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 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	: 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
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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:	
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. 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 (Dermal)	Acute toxicity (dermal), Category 4
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.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H312	Harmful 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.
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

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.