Safety Data Sheet

CalproLab Calprotectin ELISA (HRP)

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 26/11/2019 Revision date: 20/04/2023 Supersedes version of: 26/11/2019 Version: 2.0

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

1.1. Product identifier

Product form : Article
Product name : CalproLab Calprotectin ELISA (HRP)
Product code : CALP0270

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

Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : For in vitro diagnostic use.

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier
Calpro AS
Arnstein Arnebergsvei 30 norway
1366 Lysaker - NORWAY
T +47 40 00 42 79
mail@calpro.no

1.4. Emergency telephone number

Country	Official advisory body	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin Sens. 1A H317

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

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning
Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
Precautionary statements (CLP) : P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
Extra phrases : In vitro diagnostic medical devices, REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Article 1, 5.(d).

2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions.
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

The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Diagnostic kit with 9 different elements:
1. Antibody coated plate, N/A
2. Sample dilution buffer: 5-chloro-2 methyl-2H-isothiazol-3-one (CAS-No. 26172-55-4, EC-No. 247-500-7) and 2-methyl-2H isothiazol-3-one (CAS-No. 2682-20-4, EC-No. 220-239-6), (CAS-nr) 55965-84-9: 0,1%, Sodium azide CAS-No. 26628-22-8, EC-No. 247-852-1, Index-No. 011-004-00-7: <0,1%
3. Fecal extraction buffer: 5-chloro-2 methyl-2H-isothiazol-3-one (CAS-No. 26172-55-4, EC-No. 247-500-7) and 2-methyl-2H isothiazol-3-one (CAS-No. 2682-20-4, EC-No. 220-239-6), (CAS-nr) 55965-84-9: 0,1%, Sodium azide CAS-No. 26628-22-8, EC-No. 247-852-1, Index-No. 011-004-00-7: <0,1%
4. Enzyme conjugate antibody: Methylisothiazolone: (CAS-No. 2682-20-4, EC-No. 220-239-6): 0,02%, Bromonitrodioxane: (CAS-No. 30007-47-7, EC-No. 250-001-7): 0,02%
5. Standards: 5-chloro-2 methyl-2H-isothiazol-3-one (CAS-No. 26172-55-4, EC-No. 247-500-7) and 2-methyl-2H isothiazol-3-one (CAS-No. 2682-20-4, EC-No. 220-239-6), (CAS-nr) 55965-84-9: 0,1%, Sodium azide CAS-No. 26628-22-8, EC-No. 247-852-1, Index-No. 011-004-00-7: <0,1%
6. Controls: 5-chloro-2 methyl-2H-isothiazol-3-one (CAS-No. 26172-55-4, EC-No. 247-500-7) and 2-methyl-2H isothiazol-3-one (CAS-No. 2682-20-4, EC-No. 220-239-6), (CAS-nr) 55965-84-9: 0,1%, Sodium azide CAS-No. 26628-22-8, EC-No. 247-852-1, Index-No. 011-004-00-7: <0,1%
7. Washing solution: 5-chloro-2 methyl-2H-isothiazol-3-one (CAS-No. 26172-55-4, EC-No. 247-500-7) and 2-methyl-2H isothiazol-3-one (CAS-No. 2682-20-4, EC-No. 220-239-6), (CAS-nr) 55965-84-9: 0,1%
8. Substrate: 5-chloro-2 methyl-2H-isothiazol-3-one (CAS-No. 26172-55-4, EC-No. 247-500-7) and 2-methyl-2H isothiazol-3-one (CAS-No. 2682-20-4, EC-No. 220-239-6), (CAS-nr) 55965-84-9: 0,0015%, 3,3',5,5' Tetramethylbenzidin: (CAS-No. 54827-17-7, EC-No. 259-364-6): 0,03%
9. Stop Solution: Sulphuric Acid (CAS-No. 7664-93-9, EC-No. 231-639-5): 1-5%

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
sulphuric acid substance with national workplace exposure limit(s) (GB); substance with a Community workplace exposure limit (Note B)	(CAS-No.) 7664-93-9 (EC-No.) 231-639-5 (EC Index-No.) 016-020-00-8 (REACH-no) 01-2119458838-20	< 5	Skin Corr. 1A, H314
sodium azide	(CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index-No.) 011-004-00-7 (REACH-no) 01-2119457019-37	0.09 x 4	Acute Tox. 2 (Oral), H300 (ATE=27 mg/kg bodyweight) Acute Tox. 1 (Dermal), H310 (ATE=20 mg/kg bodyweight) STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	(CAS-No.) 55965-84-9 (EC-No.) 911-418-6	0.1 x 6	Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE=300 mg/kg bodyweight) Acute Tox. 3 (Inhalation:dust,mist), H331 (ATE=0.5 mg/l/4h) Skin Corr. 1C, H314 Skin Sens. 1B, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

2-methylisothiazol-3(2H)-one	(CAS-No.) 2682-20-4 (EC-No.) 220-239-6 (EC Index-No.) 613-326-00-9 (REACH-no) N/A	0.02	Acute Tox. 2 (Inhalation), H330 (ATE=0.05 mg/l/4h) Acute Tox. 3 (Dermal), H311 (ATE=87 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=40 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
5-bromo-5-nitro-1,3-dioxane	(CAS-No.) 30007-47-7 (EC-No.) 250-001-7	0.02	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Irrit. 2, H315

Specific concentration limits:		
Name	**Product identifier**	**Specific concentration limits**
sulphuric acid	(CAS-No.) 7664-93-9 (EC-No.) 231-639-5 (EC Index-No.) 016-020-00-8 (REACH-no) 01-2119458838-20	(5 ≤C < 15) Eye Irrit. 2, H319 (5 ≤C < 15) Skin Irrit. 2, H315 (15 ≤C < 100) Skin Corr. 1A, H314
2-methylisothiazol-3(2H)-one	(CAS-No.) 2682-20-4 (EC-No.) 220-239-6 (EC Index-No.) 613-326-00-9 (REACH-no) N/A	(0.0015 ≤C ≤ 100) Skin Sens. 1A, H317

Note B - Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid … %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.
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 : Never give anything by mouth to an unconscious person. Call a poison center or a doctor if you feel unwell.

First-aid measures after inhalation : Call a POISON CENTER/doctor if you feel unwell.

First-aid measures after skin contact : Wash skin with plenty of water. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after ingestion : Rinse mouth. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : No known effects from this product.

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

No specific first aid measures noted.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2), water spray, sand, earth.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable according to national regulations concerning flammable goods.

Hazardous decomposition products in case of fire : Asphyxiating gases/vapours/fumes. Carbon oxides (CO, CO2). nitrogen oxides (NOx) and sulphur oxides. Hydrogen chloride. Hydrogen bromide (HBr). Magnesium oxide fumes. sodium oxide.

5.3. Advice for firefighters

Firefighting instructions : Fight fire with normal precautions from a reasonable distance. Eliminate all ignition sources if safe to do so. Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate ventilation, especially in confined areas. Do not breathe vapour. Concerning personal protective equipment to use, see section 8.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate area. Evacuate unnecessary personnel. Only qualified personnel equipped with suitable protective equipment may intervene.

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. Prevent entry to sewers and public waters. Notify authorities if liquid 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.

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

6.4. Reference to other sections

Exposure controls and personal protection. See Section 8. 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. Handle as biohazardous infectious material.

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 : Keep in original container.

Incompatible materials : Refer to Section 10 on Incompatible Materials.

Storage temperature : 2 – 8 °C

7.3. Specific end use(s)

No additional data.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

sulphuric acid (7664-93-9)	
United Kingdom - Occupational Exposure Limits	
Local name	Sulphuric acid
WEL TWA (OEL TWA) [1]	0.05 mg/m³ mist
Remark	The mist is defined as the thoracic fraction
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

sodium azide (26628-22-8)	
United Kingdom - Occupational Exposure Limits	
Local name	Sodium azide
WEL TWA (OEL TWA) [1]	0.1 mg/m³ (as NaN3)
WEL STEL (OEL STEL)	0.3 mg/m³ (as NaN3)
Remark	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment:

8.2.2.1. Eye and face protection

Eye protection:
No special eye protection equipment recommended under normal conditions of use. Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166.

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing. Lab coat.

Hand protection:
In case of repeated or prolonged contact wear gloves. Wear rubber gloves or Latex gloves. Nitrile rubber. Neoprene. Layer thickness : 0,10mm. Breakthrough time : >480 min. STANDARD EN 374.

8.2.2.3. Respiratory protection

Respiratory protection:
Not required

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

Other information:
Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid

Colour	:	Not available
Appearance	:	Sample Dilution buffer: transparent liquid, coloured yellow Extraction solution: transparent liquid Washing solution: transparent liquid Enzyme Conjugated Antibody (IgG): transparent liquid, coloured red Substrate: transparent liquid Standards: transparent liquid, coloured yellow Controls: transparent liquid, coloured yellow Stop Solution: transparent liquid Microtiter plate: plastic coated with anti-calprotectin antibody.
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive properties	:	Not explosive.
Oxidising properties	:	Non flammable.
Explosive limits	:	Not available
Lower explosive limit (LEL)	:	Not available
Upper explosive limit (UEL)	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not self-igniting.
Decomposition temperature	:	Not available
pH	:	Sample Dilution buffer: 7.8-8.2 Extraction solution: 7.8-8.2 Washing solution: 7.8-8.2 Enzyme Conjugated Antibody (IgG): 6.0 Substrate: 3.6 - 3.8 Standards: 7.8-8.2 Controls: 7.8-8.2 Stop Solution:1.0 – 2.0 Microtiter plate: N/A
Viscosity, kinematic	:	Not available
Solubility	:	Soluble in water.
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	≈ 1 g/ml
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle size	:	Not applicable
Particle size distribution	:	Not applicable
Particle shape	:	Not applicable
Particle aspect ratio	:	Not applicable
Particle aggregation state	:	Not applicable
Particle agglomeration state	:	Not applicable
Particle specific surface area	:	Not applicable
Particle dustiness	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Additional information	:	None to our knowledge.

SECTION 10: Stability and reactivity

10.1. Reactivity

No incompatible groups noted.

10.2. Chemical stability

Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

Copper alloys. Lead compounds : Explosive vapour/air mixtures may be formed.

10.4. Conditions to avoid

None to our knowledge.

10.5. Incompatible materials

5-chloro-2 methyl-2H-isothiazol-3-one : Strong oxidizing agents, Strong reducing agents, Amines, Thiols
Methylisothiazolone: Strong oxidizing agents
Bromonitrodioxane: Strong oxidizing agents
Tetramethylbenzidin: Metals, Strong acids, Strong oxidizing agents
Sulphuric acid: Bases, Halides, Organic materials, Carbides, fulminates, Nitrates, picrates, Cyanides, Chlorates, alkali halides, Zinc salts, permanganates, e.g. potassium permanganate, Hydrogen peroxide, Azides,Perchlorates, Nitromethane, phosphorous, Reacts violently with:, cyclopentadiene, cyclopentanone oxime, nitroaryl amines, hexalithium disilicide, phosphorous(III) oxide, Powdered metals.

10.6. Hazardous decomposition products

Stable under normal temperature conditions and recommended use.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified
Additional information : Based on available data, the classification criteria are not met

2-methylisothiazol-3(2H)-one (2682-20-4)	
LD50 oral rat	40 mg/kg bodyweight
LD50 dermal rabbit	87 mg/kg bodyweight
LC50 Inhalation - Rat	< 0.2 mg/l/4h

5-bromo-5-nitro-1,3-dioxane (30007-47-7)	
LD50 oral rat	455 mg/kg

sulphuric acid (7664-93-9)	
LD50 oral rat	2140 mg/kg

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rat	50 mg/kg
LD50 dermal rabbit	20 mg/kg

Skin corrosion/irritation : Not classified
pH: Sample Dilution buffer: 7.8-8.2
Extraction solution: 7.8-8.2
Washing solution: 7.8-8.2
Enzyme Conjugated Antibody (IgG): 6.0
Substrate: 3.6 - 3.8
Standards: 7.8-8.2
Controls: 7.8-8.2
Stop Solution:1.0 – 2.0
Microtiter plate: N/A

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
pH: Sample Dilution buffer: 7.8-8.2
Extraction solution: 7.8-8.2
Washing solution: 7.8-8.2
Enzyme Conjugated Antibody (IgG): 6.0
Substrate: 3.6 - 3.8
Standards: 7.8-8.2
Controls: 7.8-8.2
Stop Solution:1.0 – 2.0
Microtiter plate: N/A

Additional information : Based on available data, the classification criteria are not met
Respiratory or skin sensitisation : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified
Additional information : Based on available data, the classification criteria are not met

3,3,5,5-tetramethylbenzidine (54827-17-7)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified
Additional information : Based on available data, the classification criteria are not met

sodium azide (26628-22-8)	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : Under normal conditions of use, no adverse effects to health have been observed.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Based on available data, the classification criteria are not met.
Hazardous to the aquatic environment, short–term (acute) : Not classified
Hazardous to the aquatic environment, long–term (chronic) : Not classified

2-methylisothiazol-3(2H)-one (2682-20-4)	
LC50 - Fish [1]	4.77 mg/l Oncorhynchus mykiss (Rainbow trout)
EC50 - Crustacea [1]	0.18 mg/l EC50 48h - Daphnia magna [mg/l]

sulphuric acid (7664-93-9)	
LC50 - Fish [1]	500 mg/l (96 hours - Brachydanio rerio, zebra-fish)
EC50 - Crustacea [1]	> 29 mg/l (48 hours - Daphnia magna)
ErC50 algae	> 100 mg/l

sodium azide (26628-22-8)	
LC50 - Fish [1]	0.7 mg/l (96 hours - Lepomis macrochirus)
EC50 - Crustacea [1]	4.2 mg/l (48 hours - Daphnia pulex)
EC50 72h - Algae [1]	0.35 mg/l Pseudokirchneriella subcapitata

12.2. Persistence and degradability

CalproLab Calprotectin ELISA (HRP)	
Persistence and degradability	No data.

2-methylisothiazol-3(2H)-one (2682-20-4)	
Biodegradation	48 – 54 % (OECD 301B method)

12.3. Bioaccumulative potential

CalproLab Calprotectin ELISA (HRP)	
Bioaccumulative potential	Unknown.

2-methylisothiazol-3(2H)-one (2682-20-4)	
Bioconcentration factor (BCF REACH)	2.3
Partition coefficient n-octanol/water (Log Pow)	-0.486

12.4. Mobility in soil

CalproLab Calprotectin ELISA (HRP)	
Ecology - soil	No data.

12.5. Results of PBT and vPvB assessment

CalproLab Calprotectin ELISA (HRP)
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. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Other adverse effects : None to our knowledge.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Handle as biohazardous infectious material.
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.
European List of Waste (LoW) code : 18 02 03 - wastes whose collection and disposal is not subject to special requirements in order to prevent infection

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID /

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not applicable

Air transport
Not applicable

Inland waterway transport
Not applicable

Rail transport
Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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 the REACH Candidate List
Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)
Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

15.1.2. National regulations

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:			
Section	**Changed item**	**Change**	**Comments**
2	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Added	
3.2	Composition/information on ingredients	Modified	

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. In vitro diagnostic medical devices, REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Article 1, 5.(d).

Full text of H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), 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
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
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H302	Harmful 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.
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.
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. 1A	Skin sensitisation, category 1A
Skin Sens. 1B	Skin sensitisation, category 1B
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.