

ELISA

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 24/02/2015 Revision date: 11/04/2022

Version/replaced version: 2.0/1.0



The following safety data sheet is valid for the Demeditec ELISA kits listed in the table below:

Trade Name	Catalogue number
IGFBP-3	DEE003A
IGFBP-2	DEE005
Leptin	DEE007
Adiponectin human	DEE009
IGF-I	DEE020
IGF-I mouse/rat	DEE025

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

1.1. Product identifier

Product form : Mixture
Product name : ELISA
UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Scientific research and development
In vitro diagnostic medical device/Buffering Agents

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
T +49 (0)431 / 71922-0 - +49 (0)431 / 71922-55
info@demeditec.de - www.demeditec.de

1.4. Emergency telephone number

Emergency number : Demeditec Diagnostics GmbH
+49 (0)431 / 71922-0

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Corrosive to metals, Category 1 H290
Skin sensitisation, Category 1A H317

Hazardous to the aquatic environment – Chronic Hazard, H412
Category 3
Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

May be corrosive to metals. May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS05 GHS07

Signal word (CLP) : Warning
Hazardous ingredients : 2-methyl-2H-isothiazol-3-one, reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
Hazard statements (CLP) : H290 - May be corrosive to metals.
H317 - May cause an allergic skin reaction.
H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP) : P261 - Avoid breathing mist/vapours/spray.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection.
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with national regulations.

2.3. Other hazards

The mixture contains substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is 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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sucrose	(CAS No) 57-50-1 (EC No) 200-334-9	5 - < 7	Not classified
Sulphuric acid ... %	(CAS No) 7664-93-9 (EC No) 231-639-5 (EC index No) 016-020-00-8 (REACH No) 01-2119458838-20-xxxx	1 - ≤ 2	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Nonylphenol, ethoxylated (substance listed as REACH Candidate)	(CAS No) 9016-45-9 (EC No) 500-024-6	0.1 - < 1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 2, H411
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (substance listed as REACH Candidate)	(CAS No) 9036-19-5	0.1 - < 1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	0.0015 - < 0.1	Acute Tox. 2 (Inhalation), H330 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-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 - < 0.06	Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Dermal), H310 Acute Tox. 3 (Oral), H301 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100)

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-xxxx	(C ≥ 0.3) Met. Corr. 1, H290 (5 ≤ C < 15) Skin Irrit. 2, H315 (5 ≤ C < 15) Eye Irrit. 2, H319 (C ≥ 15) Skin Corr. 1A, H314
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	(C ≥ 0.0015) Skin Sens. 1A, H317
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-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	(C ≥ 0.0015) Skin Sens. 1A, H317 (0.06 ≤ C < 0.6) Skin Irrit. 2, H315 (0.06 ≤ C < 0.6) Eye Irrit. 2, H319 (C ≥ 0.6) Skin Corr. 1C, H314

Full text of H-phrases: 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. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.
- First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.
- First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- First-aid measures after ingestion : Rinse mouth. Drink water as a precaution. Do NOT induce vomiting.

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

- Symptoms/injuries after skin contact : May produce an allergic reaction.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing agents that suit the environment. Extinguishing powder. Carbon dioxide. Foam. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin. Provide adequate ventilation.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Contain the spilled material by bunding (product is hazardous for 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 : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Keep in suitable, closed containers for disposal. This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Use personal protective equipment as required. Avoid contact with eyes and skin, or on clothing. Avoid breathing vapours/spray.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in corrosive resistant container with a resistant inner liner. Store in original container. Keep container tightly closed. Store in a cool, well-ventilated place. Protect from direct sunlight.
- Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs.
- Incompatible materials : Metals.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection
8.1. Control parameters

Sucrose (57-50-1)		
Ireland	Local name	Sucrose
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³
Ireland	OEL (15 min ref) (mg/m ³)	20 mg/m ³
United Kingdom	Local name	Sucrose
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	20 mg/m ³

Sulphuric acid ... % (7664-93-9)		
EU	Local name	Sulphuric acid (mist)
EU	IOELV TWA (mg/m ³)	0.05 mg/m ³
Ireland	Local name	Sulphuric acid
Ireland	OEL (8 hours ref) (mg/m ³)	0.05 mg/m ³
Ireland	Notes (IE)	IOELV
Malta	Local name	Sulphuric acid mist
Malta	Limit value - eight hours (mg/m ³)	0.05 mg/m ³
Malta	Notes (MT)	11, 12
United Kingdom	Local name	Sulphuric acid (mist)
United Kingdom	WEL TWA (mg/m ³)	0.05 mg/m ³
United Kingdom	Remark (UK)	The mist is defined as the thoracic fraction

2-methyl-2H-isothiazol-3-one (2682-20-4)	
DNEL/DMEL (Workers)	
Long-term - local effects, inhalation	0.021 mg/m ³
Acute - local effects, inhalation	0.043 mg/m ³
DNEL/DMEL (General Population)	
Long-term - systemic effects, oral	0.027 mg/kg bodyweight/day
Acute - systemic effects, oral	0.053 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.021 mg/m ³
Acute - local effects, inhalation	0.043 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	3.39 µg/l
PNEC aqua (marine water)	3.39 µg/l
PNEC aqua (intermittent, freshwater)	3.39 µg/l
PNEC aqua (intermittent, marine water)	3.39 µg/l
PNEC (Soil)	
PNEC soil	0.047 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	0.23 mg/l

8.2. Exposure controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Hand protection	: Wear protective gloves (EN 374). Nitrile rubber, 0.35 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection	: Wear closed safety glasses (EN 166).
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: In case of inadequate ventilation wear respiratory protection. Filter type P.
Environmental exposure controls	: Avoid release to the environment.

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
Melting point/freezing point	: No data available
Boiling point or initial boiling point and boiling range	: No data available
Flammability	: Non flammable
Lower and upper explosion limit	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Kinematic viscosity	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (log value)	: Not applicable
Vapour pressure	: No data available
Density and/or relative density	: No data available
Relative vapour density	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties	: No explosive properties
Oxidising properties	: No oxidising properties

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3. Possibility of hazardous reactions

May be corrosive to metals.

10.4. Conditions to avoid

No conditions to avoid known.

10.5. Incompatible materials

Metals.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

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

Acute toxicity : Not classified
Based on available data, the classification criteria are not met

Sulphuric acid ... % (7664-93-9)	
LD50 oral rat	2140 mg/kg
LC50 inhalation rat	0.375 mg/l/4h

2-methyl-2H-isothiazol-3-one (2682-20-4)	
LD50 oral rat	120 mg/kg
LD50 dermal rat	242 mg/kg
LC50 inhalation rat	0.1 mg/l/4h

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
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
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

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

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified
Based on available data, the classification criteria are not met

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

11.2. Information on other hazards

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity : Not classified
Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Sulphuric acid ... % (7664-93-9)	
LC50 fish	> 16 - < 28 mg/l 96 h, <i>Lepomis macrochirus</i>
EC50 daphnia	> 100 mg/l 48 h, <i>Daphnia magna</i>
EC50 algae	> 100 mg/l 72 h, <i>Desmodesmus subspicatus</i>

2-methyl-2H-isothiazol-3-one (2682-20-4)	
LC50 fish	4.77 mg/l 96 h, <i>Oncorhynchus mykiss</i>
EC50 daphnia	0.934 mg/l 48 h, <i>Daphnia magna</i>
EC50 algae	0.22 mg/l 120 h, <i>Pseudokirchneriella subcapitata</i>
EC50 micro-organisms	41 mg/l 3 h, activated sludge
NOEC fish	4.93 mg/l 98 d, <i>Oncorhynchus mykiss</i>
NOEC daphnia	0.044 mg/l 21 d, <i>Daphnia magna</i>
NOEC algae	0.05 mg/l 120 h, <i>Pseudokirchneriella subcapitata</i>

12.2. Persistence and degradability

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	50 % 29 d (OECD 301 B)

12.3. Bioaccumulative potential

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Log Pow	-0.486 (20 °C)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6. Endocrine disrupting properties

Components with adverse effects on the environment caused by endocrine disrupting properties: Nonylphenol, ethoxylated (9016-45-9), 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5).

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : This material and its container must be disposed of in a safe way. Do not empty into drains. Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Waste code number : The valid EWC waste code numbers are source related. The manufacturer is therefore unable to specify EWC waste codes for the articles or products used in the various sectors. The EWC codes listed are intended as a recommendation for users.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR) : UN 1760
UN-No. (IMDG) : UN 1760
UN-No. (IATA) : UN 1760

14.2. UN proper shipping name

Proper Shipping Name (ADR) : CORROSIVE LIQUID, N.O.S. (Sulphuric acid)
Proper Shipping Name (IMDG) : CORROSIVE LIQUID, N.O.S. (Sulphuric acid)
Proper Shipping Name (IATA) : Corrosive liquid, n.o.s. (Sulphuric acid)
Transport document description (ADR) : UN 1760 CORROSIVE LIQUID, N.O.S. (Sulphuric acid), 8, III, (E)
Transport document description (IMDG) : UN 1760 CORROSIVE LIQUID, N.O.S. (Sulphuric acid), 8, III
Transport document description (IATA) : UN 1760 Corrosive liquid, n.o.s. (Sulphuric acid), 8, III

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : 8
Danger labels (ADR) : 8



IMDG

Transport hazard class(es) (IMDG) : 8
Danger labels (IMDG) : 8



IATA

Transport hazard class(es) (IATA) : 8
Danger labels (IATA) : 8



14.4. Packing group

Packing group (ADR) : III
Packing group (IMDG) : III
Packing group (IATA) : III

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

14.6.1. Overland transport

Classification code (ADR) : C9
Special provisions (ADR) : 274
Limited quantities (ADR) : 5l
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T7
Portable tank and bulk container special provisions (ADR) : TP1, TP28
Tank code (ADR) : L4BN
Vehicle for tank carriage : AT
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V12
Hazard identification number (Kemler No.) : 80
Orange plates :



Tunnel restriction code (ADR) : E

14.6.2. Transport by sea

Special provisions (IMDG) : 223, 274
Limited quantities (IMDG) : 5 L
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P001, LP01
IBC packing instructions (IMDG) : IBC03
Tank instructions (IMDG) : T7
Tank special provisions (IMDG) : TP1, TP28

EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-B
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW2

14.6.3. Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y841
PCA limited quantity max net quantity (IATA) : 1L
PCA packing instructions (IATA) : 852
PCA max net quantity (IATA) : 5L
CAO packing instructions (IATA) : 856
CAO max net quantity (IATA) : 60L
Special provisions (IATA) : A3, A803
ERG code (IATA) : 8L

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 substances on the REACH candidate list: Nonylphenol, ethoxylated (9016-45-9), 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5) (Endocrine disrupting properties, REACH Article 57(f) — environment).

Contains REACH Annex XIV substances: Nonylphenol, ethoxylated (9016-45-9), 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5) (Endocrine disrupting properties, REACH Article 57(f) — environment).

Not subject to REACH authorisation (REACH authorisation exemption: used in scientific research and development, REACH Article 56 (3)).

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier.

SECTION 16: Other information

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.

Changes compared to the previous version : Complete revision, adaptation to regulation (EU) 2020/878

Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA	International Air Transport Association
IMDG	“International Maritime Dangerous Goods Code” for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
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
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/ irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Corr. 1C	Skin corrosion/irritation, Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1A	Sensitisation — Skin, category 1A
H290	May be corrosive to metals

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
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
H412	Harmful to aquatic life with long lasting effects

Safety Data Sheet (SDS), EU

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.

Controls, Calibrators

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 24/02/2015 Revision date: 11/04/2022

Version/replaced version: 2.0/1.0



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

1.1. Product identifier

Product form : Mixture
Product name : Controls, Calibrators (CONTROL 1/2 LYO / CAL A-E LYO)
UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Scientific research and development
In vitro diagnostic medical device/Controls / calibrators

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
T +49 (0)431 / 71922-0 - +49 (0)431 / 71922-55
info@demeditec.de - www.demeditec.de

1.4. Emergency telephone number

Emergency number : Demeditec Diagnostics GmbH
+49 (0)431 / 71922-0

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1A H317
Serious eye damage/eye irritation, Category 2 H319
Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411
Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction. Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07 GHS09

Signal word (CLP) : Warning
Hazardous ingredients : 2-methyl-2H-isothiazol-3-one, reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H411 - Toxic to aquatic life with long lasting effects.
Precautionary statements (CLP) : P261 - Avoid breathing dust/spray.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection.
P362 + P364 - Take off contaminated clothing and wash it before reuse.
P391 - Collect spillage.
P501 - Dispose of contents/container in accordance with national regulations.

2.3. Other hazards

The mixture contains substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is 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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethylenediaminetetraacetic acid disodium salt dihydrate	(CAS No) 6381-92-6 (EC No) 205-358-3 (REACH No) 01-2119486775-20-xxxx	1 - < 5	Acute Tox. 4 (Inhalation), H332 STOT RE 2, H373 Aquatic Chronic 3, H412

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (substance listed as REACH Candidate)	(CAS No) 9036-19-5	1 - < 2	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
Sodium azide	(CAS No) 26628-22-8 (EC No) 247-852-1 (EC index No) 011-004-00-7 (REACH No) 01-2119457019-37-xxxx	0.1 - < 1	Acute Tox. 2 (Inhalation), H330 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Oral), H300 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	0.1 - < 1	Acute Tox. 2 (Inhalation), H330 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-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 - < 0.06	Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Dermal), H310 Acute Tox. 3 (Oral), H301 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100)

Name	Product identifier	Specific concentration limits
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	(C ≥ 0.0015) Skin Sens. 1A, H317

Name	Product identifier	Specific concentration limits
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-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	(C ≥ 0.0015) Skin Sens. 1A, H317 (0.06 ≤ C < 0.6) Skin Irrit. 2, H315 (0.06 ≤ C < 0.6) Eye Irrit. 2, H319 (C ≥ 0.6) Skin Corr. 1C, H314

Full text of H-phrases: 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. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.
- First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.
- First-aid measures after eye contact : IF IN EYES: 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 : Rinse mouth. Drink water as a precaution. Do NOT induce vomiting.

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

- Symptoms/injuries after skin contact : May produce an allergic reaction.
- Symptoms/injuries after eye contact : Causes serious eye irritation.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing agents that suit the environment. Extinguishing powder. Carbon dioxide. Foam. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with eyes and skin. Avoid breathing dust. Provide adequate ventilation.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Contain the spilled material by bunding (product is hazardous for 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 mechanically (sweeping, shovelling) and collect in suitable container for disposal. Keep in suitable, closed containers for disposal. This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Use personal protective equipment as required. Avoid contact with eyes and skin, or on clothing. Avoid breathing dust.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container tightly closed. Store in a cool, well-ventilated place. Protect from direct sunlight.

Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium azide (26628-22-8)		
EU	Local name	Sodium azide
EU	IOELV LTEL (mg/m ³)	0.1 mg/m ³
EU	IOELV STEL (mg/m ³)	0.3 mg/m ³

Sodium azide (26628-22-8)		
EU	Remark (EU)	Skin
Ireland	Local name	Sodium azide (as NaN ₃)
Ireland	OEL (8 hours ref) (mg/m ³)	0.1 mg/m ³
Ireland	OEL (15 minutes ref) (mg/m ³)	0.3 mg/m ³
Ireland	Notes (IE)	Sk, IOELV
Malta	Local name	Sodium azide
Malta	Limit value - eight hours (mg/m ³)	0.1 mg/m ³
Malta	Limit value - short-term (mg/m ³)	0.3 mg/m ³
Malta	Notes (MT)	Skin
United Kingdom	Local name	Sodium azide (as NaN ₃)
United Kingdom	WEL TWA (mg/m ³)	0.1 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	0.3 mg/m ³
United Kingdom	Remark (UK)	Sk

Ethylenediaminetetraacetic acid disodium salt dihydrate (6381-92-6)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, inhalation	1.5 mg/m ³
Acute - systemic effects, inhalation	3 mg/m ³
Long-term - local effects, inhalation	1.5 mg/m ³
Acute - local effects, inhalation	3 mg/m ³
DNEL/DMEL (General Population)	
Long-term - systemic effects, oral	25 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.6 mg/m ³
Acute - local effects, inhalation	1.2 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	2.5 mg/l
PNEC aqua (marine water)	0.25 mg/l
PNEC (Soil)	
PNEC soil	1.1 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	50 mg/l

Sodium azide (26628-22-8)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, inhalation	0.164 mg/m ³
Long-term - systemic effects, dermal	46.7 µg/kg bodyweight/day
DNEL/DMEL (General Population)	
Long-term - systemic effects, oral	16.7 µg/kg bodyweight/day
Long-term - systemic effects, inhalation	29 µg/m ³
Long-term - systemic effects, dermal	16.7 µg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.35 µg/l

Sodium azide (26628-22-8)	
PNEC aqua (marine water)	15 ng/l
PNEC aqua (intermittent, freshwater)	3.5 µg/l
PNEC aqua (intermittent, marine water)	150 ng/l
PNEC (Sediments)	
PNEC sediment (freshwater)	16.7 µg/kg dwt
PNEC sediment (marine water)	0.72 µg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	30 µg/l

2-methyl-2H-isothiazol-3-one (2682-20-4)	
DNEL/DMEL (Workers)	
Long-term - local effects, inhalation	0.021 mg/m ³
Acute - local effects, inhalation	0.043 mg/m ³
DNEL/DMEL (General Population)	
Long-term - systemic effects, oral	0.027 mg/kg bodyweight/day
Acute - systemic effects, oral	0.053 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.021 mg/m ³
Acute - local effects, inhalation	0.043 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	3.39 µg/l
PNEC aqua (marine water)	3.39 µg/l
PNEC aqua (intermittent, freshwater)	3.39 µg/l
PNEC aqua (intermittent, marine water)	3.39 µg/l
PNEC (Soil)	
PNEC soil	0.047 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	0.23 mg/l

8.2. Exposure controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Hand protection	: Wear protective gloves (EN 374). Nitrile rubber, 0.35 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection	: Wear closed safety glasses (EN 166).
Skin and body protection	: Wear suitable protective clothing.
Respiratory protection	: In case of inadequate ventilation wear respiratory protection. Filter type P.
Environmental exposure controls	: Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: No data available

Odour	: No data available
Melting point/freezing point	: No data available
Boiling point or initial boiling point and boiling range	: No data available
Flammability	: No data available
Lower and upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
pH	: No data available
Kinematic viscosity	: Not applicable
Solubility	: No data available
Partition coefficient n-octanol/water (log value)	: Not applicable
Vapour pressure	: No data available
Density and/or relative density	: No data available
Relative vapour density	: Not applicable
Particle characteristics	: No data available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties	: No explosive properties
Oxidising properties	: No oxidising properties

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

No conditions to avoid known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

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

Acute toxicity : Not classified
Based on available data, the classification criteria are not met

Sodium azide (26628-22-8)	
LD50 oral rat/mouse	27 mg/kg
LD50 dermal rabbit	18 - 60 mg/kg
LC50 inhalation rat	0.054 - < 0.52 mg/l/4h

2-methyl-2H-isothiazol-3-one (2682-20-4)	
LD50 oral rat	120 mg/kg
LD50 dermal rat	242 mg/kg
LC50 inhalation rat	0.1 mg/l/4h

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

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

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified
Based on available data, the classification criteria are not met

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

11.2. Information on other hazards

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

Ethylenediaminetetraacetic acid disodium salt dihydrate (6381-92-6)	
LC50 fish	> 116 mg/l 96 h, Oncorhynchus mykiss
EC50 daphnia	> 114 mg/l 48 h, Daphnia magna
EC50 algae	> 60 mg/l 72 h, Pseudokirchneriella subcapitata
NOEC fish	≥ 35.1 mg/l 35 d, Danio rerio
NOEC daphnia	25 mg/l 21 d, Daphnia magna
NOEC algae	48.4 mg/l 72 h, Pseudokirchneriella subcapitata

Sodium azide (26628-22-8)	
LC50 fish	2.75 mg/l 96 h, Oncorhynchus mykiss
EC50 algae	0.35 mg/l 96 h, Pseudokirchneriella subcapitata

2-methyl-2H-isothiazol-3-one (2682-20-4)	
LC50 fish	4.77 mg/l 96 h, Oncorhynchus mykiss
EC50 daphnia	0.934 mg/l 48 h, Daphnia magna
EC50 algae	0.22 mg/l 120 h, Pseudokirchneriella subcapitata
EC50 micro-organisms	41 mg/l 3 h, activated sludge
NOEC fish	4.93 mg/l 98 d, Oncorhynchus mykiss
NOEC daphnia	0.044 mg/l 21 d, Daphnia magna
NOEC algae	0.05 mg/l 120 h, Pseudokirchneriella subcapitata

12.2. Persistence and degradability

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	50 % 29 d (OECD 301 B)

12.3. Bioaccumulative potential

Ethylenediaminetetraacetic acid disodium salt dihydrate (6381-92-6)	
Log Pow	-4.3 (25 °C, pH 4.5)

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Log Pow	-0.486 (20 °C)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6. Endocrine disrupting properties

Components with adverse effects on the environment caused by endocrine disrupting properties: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5).

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste treatment methods : This material and its container must be disposed of in a safe way. Do not empty into drains. Avoid release to the environment.
- Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
- Waste code number : The valid EWC waste code numbers are source related. The manufacturer is therefore unable to specify EWC waste codes for the articles or products used in the various sectors. The EWC codes listed are intended as a recommendation for users.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

- UN-No. (ADR) : UN 3077
- UN-No. (IMDG) : UN 3077
- UN-No. (IATA) : UN 3077

14.2. UN proper shipping name

- Proper Shipping Name (ADR) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1))
- Proper Shipping Name (IMDG) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1))
- Proper Shipping Name (IATA) : Environmentally hazardous substance, solid, n.o.s. (Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1))
- Transport document description (ADR) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)), 9, III, (-)
- Transport document description (IMDG) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)), 9, III, MARINE POLLUTANT
- Transport document description (IATA) : UN 3077 Environmentally hazardous substance, solid, n.o.s. (Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)), 9, III

14.3. Transport hazard class(es)

ADR

- Transport hazard class(es) (ADR) : 9
- Danger labels (ADR) : 9
- :



IMDG

- Transport hazard class(es) (IMDG) : 9

Tunnel restriction code (ADR) : -

14.6.2. Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969
Limited quantities (IMDG) : 5 kg
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P002, LP02
Special packing provisions (IMDG) : PP12
IBC packing instructions (IMDG) : IBC08
IBC special provisions (IMDG) : B3
Tank instructions (IMDG) : T1, BK1, BK2, BK3
Tank special provisions (IMDG) : TP33
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-F
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

14.6.3. Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg
Special provisions (IATA) : A97, A158, A179, A197
ERG code (IATA) : 9L

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 substances on the REACH candidate list: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5) (Endocrine disrupting properties, REACH Article 57(f) — environment).

Contains REACH Annex XIV substances: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (9036-19-5) (Endocrine disrupting properties, REACH Article 57(f) — environment).

Not subject to REACH authorisation (REACH authorisation exemption: used in scientific research and development, REACH Article 56 (3)).

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier.

SECTION 16: Other information

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.

Changes compared to the previous version : -

Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA	International Air Transport Association
IMDG	"International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
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
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/ irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Corr. 1C	Skin corrosion/irritation, Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1A	Sensitisation — Skin, category 1A
STOT RE 2	Specific target organ toxicity — Repeated exposure, 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
H332	Harmful 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
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

Safety Data Sheet (SDS), EU

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.