



SAFETY DATA SHEET

according to Regulation (EC) 1907/2006 (REACH)

Page 1

Trade name: *ELISA Kits (see below listing)*

Date of issue: 05/07/2019

CAL B (Cut-Off control), CAL C (Positive control),

Revision date: 05/07/2019

Supersedes: 09/01/2019

Version: 9.00

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Trade name: CAL B (Cut-Off control), CAL C (Positive control)

Product:

Product name	Cat.-No.
TBE/FSME IgM vet ELISA	DETCVM0440



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

1.2.1. Relevant identified uses

Use of substance/mixture: in vitro diagnostics

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2

24145 Kiel

Germany

info@demeditec.de

1.4. Emergency telephone number

Emergency number: +49 (0)431/71922-0 (available during business hours from 8 a.m. to 4:30 p.m.)

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2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1

Full text of H statements: see section 16

Adverse physicochemical, human health and environmental effect

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

Hazardous ingredients

Hazard statements (CLP)

Warning

2-methyl-2H-isothiazol-3-one

H317: May cause an allergic skin reaction.

P261: Avoid breathing mist, vapours, spray.

P280: Wear protective gloves.

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Comments: Solvent mixture with additives

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 (CLP)
2-methyl-2H-isothiazol-3-one	CAS-No. 2682-20-4 EC-No. 220-239-6	0.01 – 0.02	Acute Tox. 3 (Oral), H301 Acute Tox.3 (Dermal), H311 Acute Tox.2 (Inhalation: dust, mist, H330 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410



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Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-methyl-2H-isothiazol-3-one	CAS-No. 2682-20-4 EC-No. 220-239-6	(0.00015 = < C < 0.0015) EUH208 (0.0015 = < C < 100) Skin Sens. 1, H317

Full text of H-statements: see section 16

4. FIRST AID MEASURES

4.1. Description of the first aid measures

First-aid measures general:	In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation:	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact:	Take off contaminated clothing. Wash skin with plenty of water. Cover wounds with sterile bandage. Get medical advice if skin irritation persists. If skin irritation or rash occurs: Get medical advice/ attention
First-aid measures after eye contact:	Rinse eyes with water as a precaution. Remove contact lenses, if present and easy to do. Continue rinsing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
First-aid measures after ingestion:	Rinse mouth out with water. Drink plenty of water. Do NOT induce vomiting. Call a doctor. 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: May cause an allergic skin reaction.

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

Treat symptomatically.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:	Not combustible. Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam Carbon dioxide.
Unsuitable extinguishing media:	Strong water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire: Release of harmful/irritant gases/vapours. Nitrogen oxides.

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.
Other information:	Do not allow run-off from the fire-fighting to enter drains or water courses. Disposal must be done according to official regulations.



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6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see section 8.

Emergency procedures: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public water.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Wash away remainder with plenty of water.

Other information: Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment. Avoid breathing mist, vapours, spray.

Hygiene measures: Contaminated work clothing should not be allowed out of workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a well-ventilated place. Keep cool!

Information about storage in one common storage facility: Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

In vitro diagnostics.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

2-methyl-2H-isothiazol-3-one (2682-20-4)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	0.043 mg/m ³
Long-term - local effects, inhalation	0.021 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, oral	0.053 mg/kg bodyweight
Acute - local effects, inhalation	0.043 mg/m ³
Long-term - systemic effects, oral	0.027 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.021 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
2-methyl-2H-isothiazol-3-one (2682-20-4)	
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:

Keep workplace clean and tidy as much as possible. Ensure good ventilation of work station.

Hand protection:

Chemically resistant protective gloves. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear.

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35	3 (> 0.65)	EN ISO 374

Eye protection:

Chemical goggles. EN 166

Skin and body protection:

Wear suitable protective clothing. EN 340. EN 13034

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Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Filter: ABEK-P2. EN 143.
Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust.

Environmental exposure controls:

Avoid release to the environment.

Other information

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state:	liquid
Colour:	yellow
Odour:	odourless
Odour threshold:	no data available.
pH:	6.3 – 7.5 (20°C)
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:	water: miscible
Log Pow:	no data available
Viscosity, kinematic:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	product is not explosive
Oxidising properties:	non oxidizing
Explosive limits:	no data available

10. STABILITY AND REACTIVITY**10.1. Reactivity**

No additional information available.

10.2. Chemical stability

No decomposition if stored normally.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

heat



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10.5. Incompatible materials

No additional information available.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

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

2-methyl-2H-isothiazol-3-one (2682-20-4)	
LD50 oral rat	120 mg/kg bodyweight (EPA OPPTS 870.1100)
LD50 dermal rat	242 mg/kg bodyweight (OECD 402 method)
LC50 inhalation rat (Dust/Mist - mg/l/4h)	0.1 mg/l/4h (OECD 403 method)

Skin corrosion/irritation: not classified (Based on available data, the classification criteria are not met)
ph: 6.3 – 7.5 (20°C)
Additional information: Repeated or prolonged skin contact may cause irritation
Serious eye damage/irritation: not classified (Based on available data, the classification criteria are not met)
ph: 6.3 – 7.5 (20°C)
Additional information: Slight eye irritant upon direct contact
Respiratory or skin sensitisation: May cause an allergic 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)
STOT-single exposure: not classified (Based on available data, the classification criteria are not met)
STOT-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)



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12. ECOLOGICAL INFORMATION

12.1. Toxicity

Acute aquatic toxicity: not classified (Based on available data, the classification criteria are not met)
Chronic aquatic toxicity: not classified (Based on available data, the classification criteria are not met)

2-methyl-2H-isothiazol-3-one (2682-20-4)	
LC50 fish 1	4.77 mg/l (96 h; Oncorhynchus mykiss; (OECD 203 method))
EC50 Daphnia 1	0.934 mg/l (48 h; Daphnia magna; (OECD 202 method))
EC50 72h algae	0.157 mg/l (72 h, Pseudokirchneriella Subcapita)
ErC50 (algae)	0.072 mg/l (OECD 201 method)
NOEC chronic fish	4.93 mg/l (Oncorhynchus mykiss)
NOEC chronic crustacea	0.044 mg/l (OECD 211 method)
NOEC chronic algae	0.05 mg/l (OECD 201 method)

12.2. Persistence and degradability

CAL B (Cut-Off control), CAL C (Positive control)	
Persistence and degradability	No additional information available

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Persistence and degradability	Not readily biodegradable. (OECD 301B method). (EECD 301D method).

12.3. Bioaccumulative potential

CAL B (Cut-Off control), CAL C (Positive control)	
Log Pow	Not applicable
Bioaccumulative potential	No additional information available

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Log Pow	-0.486 (20 °C)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

CAL B (Cut-Off control), CAL C (Positive control)	
Ecology - soil	No additional information available

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Surface tension	68.8 mN/m (19°C, EEC Method A5)
Ecology - soil	Low mobility (soil).

12.5. Results of PBT and vPvB assessment

CAL B (Cut-Off control), CAL C (Positive control)	
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

Other adverse effects: No additional information available.



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13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods:

Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

Product/Packaging disposal recommendations:

Dirty containers cannot be handled as normal waste. Disposal must be done according to official regulations.

European List of Waste (LoW) code:

16 05 06* - laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals

HP Code:

15 01 02 – plastic packaging

HP13 – “Sensitising”: Waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.

14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable



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15. REGULATORY INFORMATION

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006

3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

CAL B, **CAL C**

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances

Contains no substances subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Substance(s) are not subject to Regulation (EC) No. 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

Other information, restriction and prohibition regulation:

Take note of Directive 94/33/EC on the protection of young people at work.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.



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16. OTHER INFORMATION

Indication of changes

Section	Changed item	Change	Comments
	General revision		
1.1	Product name – Trade name	Modified	
3.2	Composition/information on ingredients	Modified	
12.	Ecological information	Modified	

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
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No. 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
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
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Regulation (EC) No. 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources:

MSDS of the supplier. IUCLID-Dossier from ECHA.

Department issuing data specification sheet:

R&D department

Contact person:

R&D department



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Full text of H- and EUH-statements:

Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
EUH208	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



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1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Trade name: ENZ CONJ

Products: See first page

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

1.2.1. Relevant identified uses

Use of substance/mixture: in vitro diagnostics

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2

24145 Kiel

Germany

info@demeditec.de

1.4. Emergency telephone number

Emergency number: +49 (0)431/71922-0 (available during business hours from 8 a.m. to 4:30 p.m.)

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effect

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

No labelling required

2.3. Other hazards

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Comments: Solvent mixture with additives

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II



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4. FIRST AID MEASURES

4.1. Description of the first aid measures

First-aid measures general:	In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation:	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact:	Take off contaminated clothing. Wash skin with plenty of water. Cover wounds with sterile bandage. Get medical advice if skin irritation persists.
First-aid measures after eye contact:	Remove contact lenses, if present and easy to do. Continue rinsing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
First-aid measures after ingestion:	Rinse mouth out with water. Drink plenty of water. Do NOT induce vomiting. Call a doctor.

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

Symptoms/effects after skin contact: May cause skin irritation.

Symptoms/effects after eye contact: May cause eye irritation

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

Treat symptomatically.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Not combustible. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: No information available.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire: release of harmful/irritant gases/vapours. Nitrogen oxides.

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.

Other information: Do not allow run-off from the fire-fighting to enter drains or water courses. Disposal must be done according to official regulations.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see section 8.

Emergency procedures: Ventilate spillage area.

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 sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up:

Take up liquid spill into absorbent material, e.g.: sand, saw dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information:

Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling:

Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.

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 dry, cool, well-ventilated area.

Information about storage in one common storage facility:

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

In vitro diagnostics.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Keep workplace clean and tidy as much as possible. Ensure good ventilation of work station.

Hand protection:

Chemically resistant protective gloves. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear.

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35		EN 374

Eye protection:

Chemical goggles. EN 166

Skin and body protection:

Wear suitable protective clothing



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Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. P2. EN 143.

Environmental exposure controls:

Avoid release to the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	various
Odour:	characteristic
Odour threshold:	no data available.
pH:	7 – 7.4 (20°C)
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:	water: miscible
Log Pow:	no data available
Viscosity, kinematic:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	product is not explosive
Oxidising properties:	no data available
Explosive limits:	no data available

9.2. Other information

VOC content: 0 %

10. STABILITY AND REACTIVITY

10.1. Reactivity

No additional information available.

10.2. Chemical stability

No decomposition if stored normally.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

heat

10.5. Incompatible materials

No additional information available.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.



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11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (oral):	not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal):	not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation):	not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation:	not classified (Based on available data, the classification criteria are not met) ph: 7 – 7.4 (20°C)
Additional information:	Repeated or prolonged skin contact may cause irritation
Serious eye damage/irritation:	not classified (Based on available data, the classification criteria are not met) ph: 7 – 7.4 (20°C)
Additional information:	Slight eye irritant upon direct contact
Respiratory or skin sensitisation:	not classified (Based on available data, the classification criteria are not met)
Additional information:	May cause sensitisation of susceptible persons by skin contact.
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)
STOT-single exposure:	not classified (Based on available data, the classification criteria are not met)
STOT-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)



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12. ECOLOGICAL INFORMATION

12.1. Toxicity

Acute aquatic toxicity: not classified (Based on available data, the classification criteria are not met)

Chronic aquatic toxicity: not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

ENZ CONJ	
Persistence and degradability	No additional information available

12.3. Bioaccumulative potential

ENZ CONJ	
Bioaccumulative potential	No additional information available

12.4. Mobility in soil

ENZ CONJ	
Ecology - soil	No additional information available

12.5. Results of PBT and vPvB assessment

ENZ CONJ	
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

Other adverse effects: No additional information available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods: Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

Product/Packaging disposal recommendations: Dirty containers cannot be handled as normal waste. Disposal must be done according to official regulations.

European List of Waste (LoW) code: 16 05 06* - laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals
15 01 02 – plastic packaging



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14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable

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

VOC content: 0%

Other information, restriction and prohibition regulation:

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on voluntary basis.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.



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16. OTHER INFORMATION

Indication of changes

Section	Changed item	Change	Comments
9.1	Odour	modified	
9.2	VOC – Swiss ordinance	modified	
15.1	Additional information	added	

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by In-land Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No. 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NO-AEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Regulation (EC) No. 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources: MSDS of the supplier. IUCLID-Dossier from ECHA.

Department issuing data specification

sheet: R&D department

Contact person: R&D department

Full text of H- and EUH-statements:

EUH208	Contains. May produce an allergic reaction
EUH210	Safety data sheet available on request

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



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1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Trade name:

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Products: See first page

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

1.2.1. Relevant identified uses

Use of substance/mixture: in vitro diagnostics

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2

24145 Kiel

Germany

info@demeditec.de

1.4. Emergency telephone number

Emergency number: +49 (0)431/71922-0 (available during business hours from 8 a.m. to 4:30 p.m.)

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effect

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

EUH-statements: EUH210 – Safety data sheet available on request

2.3. Other hazards

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

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]
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	< 3	Skin. Corr. 1A, H314



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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-xxxx	(5=<C <15) Eye Irrit. 2, H319 (5=<C <15) Skin Irrit. 2, H315 (C>= 15) Skin Corr. 1A, H314

Full text of H-statements: see section 16

4. FIRST AID MEASURES

4.1. Description of the first aid measures

First-aid measures general:	In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation:	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact:	Take off contaminated clothing. Wash skin with plenty of water. Cover wounds with sterile bandage. Get medical advice if skin irritation persists.
First-aid measures after eye contact:	Remove contact lenses, if present and easy to do. Continue rinsing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
First-aid measures after ingestion:	Rinse mouth out with water. Drink plenty of water. Do NOT induce vomiting. Call a doctor.

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

Symptoms/effects after skin contact: May cause slight irritation.

Symptoms/effects after eye contact: May cause eye irritation.

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

Treat symptomatically.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Not combustible. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: No information available.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire: release of harmful/irritant gases/vapours. Sulphur oxides.

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.

Other information: Do not allow run-off from the fire-fighting to enter drains or water courses. Disposal must be done according to official regulations.



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6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see section 8.

Emergency procedures: Ventilate spillage area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information: Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.

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 dry, cool, well-ventilated area.

Information about storage in one common storage facility: Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

In vitro diagnostics.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

sulphuric acid (7664-93-9)		
EU	Local name	Sulphuric acid (mist)
EU	IOELV TWA (mg/m ³)	0.05 mg/m ³
EU	Regulatory reference	COMMISSION DIRECTIVE 2009/161/EU
United Kingdom	Local name	Sulphuric acid
United Kingdom	WEL TWA (mg/m ³)	0.05 mg/m ³ mist
United Kingdom	Remark (WEL)	The mist is defined as the thoracic fraction
United Kingdom	Regulatory reference	EH40. HSE

8.2. Exposure controls

Appropriate engineering controls:

Keep workplace clean and tidy as much as possible. Ensure good ventilation of work station.

Materials for protective clothing:

Use protective clothing

Hand protection:

Chemically resistant protective gloves. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear.

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35		EN 374

Eye protection:

Chemical goggles. EN 166

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear respiratory protection. Combination filter: ABEK. EN 143.

Environmental exposure controls:

Avoid release to the environment.

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless
Odour:	odourless
Odour threshold:	no data available.
pH:	1
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:	water: miscible
Log Pow:	no data available
Viscosity, kinematic:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	product is not explosive
Oxidising properties:	no data available
Explosive limits:	no data available

9.2. Other information

Other properties:	this product is corrosive to metals.
Additional information:	may be corrosive to metals.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No additional information available.

10.2. Chemical stability

No decomposition if stored normally.

10.3. Possibility of hazardous reactions

Reacts violently with: metals

10.4. Conditions to avoid

heat

10.5. Incompatible materials

metals.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.



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11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (oral):	not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal):	not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation):	not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation:	not classified (Based on available data, the classification criteria are not met) ph: 1
Additional information:	Repeated or prolonged skin contact may cause irritation
Serious eye damage/irritation:	not classified (Based on available data, the classification criteria are not met) ph: 1
Additional information:	Slight eye irritant upon direct contact
Respiratory or skin sensitisation:	not classified (Based on available data, the classification criteria are not met)
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)
STOT-single exposure:	not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure:	not classified (Based on available data, the classification criteria are not met)

sulphuric acid (7664-93-9)

LOAEC (inhalation, rat, vapour, 90 days) | 0.3 mg/m³ (6h/d: 28 d; (OECD 412 method), Aerosol)

Aspiration hazard:	not classified (Based on available data, the classification criteria are not met)
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12. ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology – general: before neutralisation, the product may represent a danger to aquatic organisms

Acute aquatic toxicity: not classified (Based on available data, the classification criteria are not met)

Chronic aquatic toxicity: not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

Stopping Solution	
Persistence and degradability	No additional information available

sulphuric acid (7664-93-9)	
Persistence and degradability	No additional information available

12.3. Bioaccumulative potential

Stopping Solution	
Bioaccumulative potential	No additional information available

sulphuric acid (7664-93-9)	
Bioaccumulative potential	not relevant.

12.4. Mobility in soil

Stopping Solution	
Ecology - soil	No additional information available

sulphuric acid (7664-93-9)	
Ecology - soil	No additional information available

12.5. Results of PBT and vPvB assessment

Stopping Solution
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

Other adverse effects: No additional information available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods: Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

Product/Packaging disposal recommendations: Dirty containers cannot be handled as normal waste. Disposal must be done according to official regulations.

European List of Waste (LoW) code: 16 05 06* - laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals
15 01 02 – plastic packaging



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14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable

15. REGULATORY INFORMATION

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No. 1907/2006:

3 Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No. 1272/2008	sulphuric acid
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3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No. 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	sulphuric acid
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Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

For the following substances of this mixture a chemical safety assessment has been carried out

sulphuric acid



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16. OTHER INFORMATION

Indication of changes

Section	Changed item	Change	Comments
9.2	additional information	added	
15.1	additional information	added	

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
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No. 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NO-AEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Regulation (EC) No. 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources: MSDS of the supplier. IUCLID-Dossier from ECHA.

Department issuing data specification

sheet: R&D department

Contact person: R&D department

Full text of H- and EUH-statements:

Skin Corr. 1A	Skin corrosion/irritation, Category 1A
EUH208	Causes severe skin burns and eye damage.
EUH210	Safety data sheet available on request

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



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1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Trade name:

SUB TMB

Products: See first page

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

1.2.1. Relevant identified uses

Use of substance/mixture: Substrate solution for immunoassays

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2

24145 Kiel

Germany

info@demeditec.de

1.4. Emergency telephone number

Emergency number: +49 (0)431/71922-0 (available during business hours from 8 a.m. to 4:30 p.m.)

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effect

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

No labelling applicable.

2.3. Other hazards

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Comments: Nonhazardous mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II



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4. FIRST AID MEASURES

4.1. Description of the first aid measures

First-aid measures general: When in doubt or if symptoms are observed, get medical advice

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing. If symptoms persist, call a physician.

First-aid measures after skin contact: Take off contaminated clothing. Wash skin with plenty of water.

First-aid measures after eye contact: Rinse thoroughly and plentifully with water, also under the eyelids.

First-aid measures after ingestion: Rinse mouth out with water. Drink plenty of water. Call a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: No information available.

5.2. Special hazards arising from the substance or mixture

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

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.

Other information: Do not allow run-off from the fire-fighting to enter drains or water courses. Disposal must be done according to official regulations.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see section 8.

Emergency procedures: Ventilate spillage area. Avoid contact with skin and eyes. 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 sub-soil penetration. Prevent entry to sewers and public waters.



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6.3. Methods and material for containment and cleaning up

Methods for cleaning up:

Take up liquid spill into absorbent material, e.g.: sand, saw dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Notify authorities if product enters sewers or public waters.

Other information:

Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

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.

Hygiene measures:

Separate working clothes from town clothes. Launder separately. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions:

Store in a dry place. Store in a closed container. Containers which are opened should be properly resealed and kept upright to prevent leakage. Store in a well-ventilated place. Keep cool.

Storage temperature:

2-8°C

Information about storage in one common storage facility:

Keep away from food, drink and animal feeding stuffs.

Storage area:

Protect from light: Protect from moisture. Store away from heat.

7.3. Specific end use(s)

Follow the directions.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Keep workplace clean and tidy as much as possible. Ensure good ventilation of work station.

Hand protection:

In case of repeated or prolonged contact wear gloves. Chemically resistant protective gloves. EN374
Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear.

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Nitrile rubber	6 (> 480 minutes)	>0,28	No additional information available	EN ISO 374
Chemically resistant protective gloves	Natural rubber	6 (> 480 minutes)	>0,22	No additional information available	EN ISO 374

Eye protection:

Safety goggles, EN 166

Skin and body protection:

Wear suitable protective clothing. EN 14605

Respiratory protection:

In case of inadequate ventilation, wear respiratory protection. Breathing apparatus with filter. Combination filter: ABEK. EN 143. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust. In case of insufficient ventilation, wear suitable respiratory equipment.

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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9. PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state:	liquid
Colour:	colourless
Odour:	characteristic
Odour threshold:	no data available.
pH:	3.5 – 4
Relative evaporation rate (butylacetate = 1)	no data available
Melting point:	not applicable
Freezing point:	no data available
Boiling point:	101 °C
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
Density	1.011 g/cm ³
Solubility:	Water: solubleMiscible
Log Pow:	no data available
Viscosity, kinematic:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	product is not explosive
Oxidising properties:	non oxidizing
Explosive limits:	no data available

9.2. Other information

Other properties: No additional information available.

10. STABILITY AND REACTIVITY**10.1. Reactivity**

No additional information available.

10.2. Chemical stability

No decomposition if stored normally.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Water, humidity. All heat sources, including direct sunlight

10.5. Incompatible materials

Strong oxidizing agent. Metals. Metallic salts.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.



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11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (oral):	not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal):	not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation):	not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation:	not classified (Based on available data, the classification criteria are not met) pH: 3.5– 4
Additional information:	Repeated or prolonged skin contact may cause irritation
Serious eye damage/irritation:	not classified (Based on available data, the classification criteria are not met) pH: 3.5– 4
Respiratory or skin sensitisation:	not classified (Based on available data, the classification criteria are not met)
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:	May damage the unborn child.
STOT-single exposure:	not classified (Based on available data, the classification criteria are not met)
STOT-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)

12. ECOLOGICAL INFORMATION

12.1. Toxicity

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

12.2. Persistence and degradability

SUB TMB	
Persistence and degradability	No additional information available

12.3. Bioaccumulative potential

SUB TMB	
Bioaccumulative potential	No additional information available

12.4. Mobility in soil

SUB TMB	
Ecology - soil	No additional information available



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12.5. Results of PBT and vPvB assessment

SUB TMB
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

Component	
N-methyl-2-pyrrolidone (872-50-4)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects: No additional information available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods: Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

Product/Packaging disposal recommendations: Dirty containers cannot be handled as normal waste. Disposal must be done according to official regulations. Recycle or dispose of in compliance with current legislation.

14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable



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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

Contains no substances subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and the import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

Other information, restriction and prohibition regulations: A safety data sheet is not required for this product under Article 31 of REACH. This product Safety Information Sheet has been created on a voluntary basis.

15.1.2. National regulations

United Kingdom

National regulations: Take note of Directive 92/85/EC on the safety of health of pregnant workers at work.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.



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16. OTHER INFORMATION

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
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No. 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NO-AEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Regulation (EC) No. 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources:

MSDS of the supplier.

Department issuing data specification sheet:

R&D department

Contact person:

R&D department

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

1.1. Product identifier

Trade name:

WASH SOLN

Products: See first page

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: In vitro diagnostics

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2

24145 Kiel

Germany

info@demeditec.de

1.4. Emergency telephone number

Emergency number: +49 (0)431/71922-0 (available during business hours from 8 a.m. to 4:30 p.m.)

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Comments: Aqueous solution of special active agents

The mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II



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4. SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general:	In all cases of doubt, or when symptoms persist, seek medical attention
First-aid measures after inhalation:	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact:	Take off contaminated clothing. Wash skin with plenty of water. Cover wounds with sterile bandage. Get medical advice if skin irritation persists.
First-aid measures after eye contact:	Remove contact lenses, if present and easy to do. Continue rinsing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
First-aid measures after ingestion:	Rinse mouth out with water. Drink plenty of water. Do NOT induce vomiting. Call a doctor.

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

Symptoms/ effects after skin contact: May cause slight irritation.

Symptoms/ effects after eye contact: May cause eye irritation.

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

Treat symptomatically.

5. SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Not combustible. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: No information available.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire: release of harmful/ irritant gases/ vapours. Nitrogen oxides.

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.

Other information: Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

6. SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see section 8.

Emergency procedures: Ventilate spillage area.

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 sub-soil penetration. Prevent entry to sewers and public waters.



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6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal.

Other information: Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

7. SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Avoid contact with skin and eyes.

Hygiene measures: Wear Personal protective equipment. 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 well-ventilated place. Keep cool.

Information about storage in one Common storage facility: Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

In vitro diagnostics.

8. SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1. Control parameters

No additional information available.

8.2. Exposure controls

Appropriate engineering controls: Keep workplace clean and tidy as much as possible. Ensure good ventilation of the work station.

Hand protection:

Chemically resistant protective gloves. Choosing the proper glove is decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35		EN 374

Eye protection: Chemical goggles. EN 166

Skin and body protection: Wear suitable protective clothing

Respiratory protection: In case of inadequate ventilation wear respiratory protection. P1. EN 143.

Environmental exposure controls: Avoid release to the environment.



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9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	colourless
Odour:	odourless
Odour threshold:	No data available
pH:	7 – 7.4 (20 C)
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:	Water: Miscible
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	Product is not explosive.
Oxidising properties:	No data available
Explosive limits:	No data available

9.2. Other information

VOC content: 0 %

10. SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No additional information available.

10.2. Chemical stability

No decomposition if stored normally.

10.3. Possibility of hazardous reactions:

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Heat.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.



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11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (oral):	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal):	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation):	Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/ irritation:	Not classified (Based on available data, the classification criteria are not met) pH: 7 – 7.4 (20 C)
Additional information:	Repeated or prolonged skin contact may cause irritation
Serious eye damage/ irritation:	Not classified (Based on available data, the classification criteria are not met) pH: 7 – 7.4 (20 C)
Additional information:	Slight eye irritant upon direct contact.
Respiratory or skin sensitization:	Not classified (Based on available data, the classification criteria are not met)
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)
STOT-single exposure:	Not classified (Based on available data, the classification criteria are not met)
STOT-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)



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12. SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology – general:

Before neutralization, the product may represent a danger to aquatic organisms.

Acute aquatic toxicity:

Not classified (Based on available data, the classification criteria are not met)

Chronic aquatic toxicity:

Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

WASH SOLN

Persistence and degradability

No additional information available.

12.3. Bioaccumulative potential

WASH SOLN

Bioaccumulative potential

No additional information available.

12.4. Mobility in soil

WASH SOLN

Ecology - soil

No additional information available.

12.5. Results of PBT and vPvB assessment

WASH SOLN

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

Other adverse effects:

No additional information available.

13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods:

Disposal must be done according to official regulations. European waste Catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

Product/ Packaging disposal recommendations:

Dirty containers cannot be handled as normal waste. Disposal must be done according to official regulations.

European List of Waste (LoW) code:

16 05 06* - laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals
15 01 02 – plastic packaging



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14. SECTION 14: TRANSPORT INFORMATION

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

ADR	IMDG	IATA	AND	RID
14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

15. 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

VOC content: 0 %

Other information, restriction and prohibition

A safety data sheet is not required for this product under Article 31 of REACH.

regulations:

This product Safety Information Sheet has been created on a voluntary basis.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out



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Trade name: *ELISA Kits (see first page)*

WASH SOLN

Date of issue: 09/22/ 2017

Revision date: 09/22/2017

Supersedes: 09/19/2016

Version: 7.00

16. SECTION 16: OTHER INFORMATION

Indication of changes:

Section	Changed item	Change	Comments
9.1	Colour	Modified	
9.2	VOC – Swiss ordinance	Modified	
15.1	Additional information	Added	

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
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
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
OECD	Organization for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources: MSDS of the supplier. IUCLID-Dossier from ECHA.

Department issuing data specification sheet:

R&D department

Contact person:

R&D department

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.

Trade name: *ELISA Kits (see first page)*
SAM DIL, CAL A (Negative Control)

Date of issue: 05/07/2019
 Revision date: 05/07/2019
 Supersedes: 09/01/2019
 Version: 9.00

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Trade name: SAM DIL, CAL A (Negative Control)
 Products: See first page

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

1.2.1. Relevant identified uses

Use of substance/mixture: in vitro diagnostics

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Demeditec Diagnostics GmbH
 Lise-Meitner-Str. 2
 24145 Kiel
 Germany
info@demeditec.de

1.4. Emergency telephone number

Emergency number: +49 (0)431/71922-0 (available during business hours from 8 a.m. to 4:30 p.m.)

2. HAZARDS IDENTIFICATION

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

Skin sensitisation, Category 1 H317
 Full text of H statements: see section 16

Adverse physicochemical, human health and environmental effect

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP)	Warning
Hazardous ingredients	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no.0247-500-7), and 2-methyl-2H-isothiazol-3-one (EC no. 220-239-6) (3:1)
Hazard statements (CLP)	H317: May cause an allergic skin reaction.
Precautionary statements (CLP)	P261: Avoid breathing mist, vapours, spray. P280: Wear protective gloves. P302+352: IF ON SKIN: Wash with plenty of soap and water. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse.
EUH-statements	EUH032 – Contact with acids liberates very toxic gas.



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2.3. Other hazards

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Comments: Solvent mixture with additives

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
sodium azide substance with a Community workplace exposure limit substance with national workplace exposure limit(s) (GB)	(CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index-No.) 011-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation:dust,mist), H330 STOT RE 2, H373 Aquatic Acute 1, H400 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	< 0.1	Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
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 =<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	

Specific concentration limits:

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	(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-statements: see section 16



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4. FIRST AID MEASURES

4.1. Description of the first aid measures

First-aid measures general:	In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation:	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact:	Take off contaminated clothing. Wash skin with plenty of water. Cover wounds with sterile bandage. Get medical advice if skin irritation persists. Wash skin with plenty of water. If skin irritation or rash occurs: get medical advice/attention.
First-aid measures after eye contact:	Remove contact lenses, if present and easy to do. Continue rinsing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Rinse eyes with water as a precaution.
First-aid measures after ingestion:	Rinse mouth out with water. Drink plenty of water. Do NOT induce vomiting. Call a doctor. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects:	No additional information available.
Symptoms/effects after skin contact:	May cause slight irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact:	May cause eye irritation.

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

Treat symptomatically.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:	Water spray. Dry powder. Foam. Carbon dioxide. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media:	Strong water jet

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire:	Toxic fumes may be released. Nitrogen oxides. Carbon monoxide. Carbon dioxide.
---	--

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.
Other information:	Do not allow run-off from the fire-fighting to enter drains or water courses. Disposal must be done according to official regulations.



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6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see section 8.

Emergency procedures: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Wash away remainder with plenty of water.

Other information: Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

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, vapours, spray.

Hygiene measures: Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a well-ventilated place. Keep cool!

Information about storage in one common storage facility: Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

In vitro diagnostics.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

sodium azide (26628-22-8)		
EU	Local name	Sodium azide
EU	IOELV TWA (mg/m ³)	0.1 mg/m ³
EU	IOELV STEL (mg/m ³)	0.3 mg/m ³
EU	Notes	Skin
EU	Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC
sodium azide (26628-22-8)		
United Kingdom	Local name	Sodium azide
United Kingdom	WEL TWA (mg/m ³)	0.1 mg/m ³ (as NaN ₃)
United Kingdom	WEL STEL (mg/m ³)	0.3 mg/m ³ (as NaN ₃)
United Kingdom	Remark (WEL)	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)
United Kingdom	Regulatory reference	EH40/2005 (Third edition, 2018). HSE

8.2. Exposure controls

Appropriate engineering controls:

Keep workplace clean and tidy as much as possible. Ensure good ventilation of work station.

Hand protection:

Chemically resistant protective gloves. Gloves must be replaced after each use and whenever signs of wear or perforation appear. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. EN 374

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35	3 (< 0.65)	EN ISO 374

Eye protection:

Chemical goggles. EN 166

Skin and body protection:

Wear suitable protective clothing. EN 340. EN 13034

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory protection. Filter. ABEK-P2. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust. EN 143.

Environmental exposure controls:

Avoid release to the environment.

Other information

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.



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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	various
Odour:	odourless
Odour threshold:	no data available.
pH:	7 – 8.2 (20°C)
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:	water: miscible
Log Pow:	no data available
Viscosity, kinematic:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	product is not explosive
Oxidising properties:	no data available
Explosive limits:	no data available

9.2. Other information

VOC content: 0 %



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10. STABILITY AND REACTIVITY

10.1. Reactivity

No additional information available.

10.2. Chemical stability

No decomposition if stored normally.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Contact with acids liberates very toxic gas.

10.4. Conditions to avoid

heat

10.5. Incompatible materials

No additional information available. Acids.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

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

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg bodyweight
LD50 dermal rabbit	18 - 60 mg/kg bodyweight
LC50 inhalation rat (Dust/Mist - mg/l/4h)	0.054 - 0.52 mg/l/4h (EPA OPPTS 870.1300 (Acute inhalation toxicity))

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) (55965-84-9)	
LD50 oral rat	53 mg/kg
LD50 dermal rat	660 mg/kg
LC50 inhalation rat (Dust/Mist - mg/l/4h)	2.36 mg/l/4h

Skin corrosion/irritation: not classified (Based on available data, the classification criteria are not met)
ph: 7 – 8.2 (20°C)
Additional information: Repeated or prolonged skin contact may cause irritation
Serious eye damage/irritation: not classified (Based on available data, the classification criteria are not met)
ph: 7 – 8.2 (20°C)
Additional information: Slight eye irritant upon direct contact
Respiratory or skin sensitisation: not classified (Based on available data, the classification criteria are not met)



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[SAM] [DIL], [CAL] [A] (Negative Control)

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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)
STOT-single exposure: not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure: not classified (Based on available data, the classification criteria are not met)

sodium azide (26628-22-8)	
LOAEL (oral, rat, 90 days)	10 mg/kg bodyweight/day (Impairment of the nervous system)
NOAEL (oral, rat, 90 days)	5 mg/kg bodyweight/day (Impairment of the nervous system)

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

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology – general: May cause pH changes in aqueous ecological systems.
Acute aquatic toxicity: not classified (Based on available data, the classification criteria are not met)
Chronic aquatic toxicity: not classified (Based on available data, the classification criteria are not met)

sodium azide (26628-22-8)	
LC50 fish 1	0.68 mg/l (OECD 203 method)
EC50 Daphnia 1	400 µg/l Freshwater
EC50 Daphnia 2	150 µg/l SALT WATER
EC50 96h algae (1)	0.348 mg/l (OECD 201 method)

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) (55965-84-9)	
LC50 fish 1	0.22 mg/l (96h, Oncorhynchus mykiss, (OECD 201 method))
EC50 Daphnia 1	0.1 mg/l (48h, Daphnia magna, (OECD 202 method))
ErC50 (algae)	0.048 mg/l (72h, Pseudokirchneriella subcapitata, (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d, Oncorhynchus mykiss, (OECD 210 method))
NOEC chronic crustacea	0.004 mg/l (21 d, Daphnia magna, (OECD 211 method))

12.2. Persistence and degradability

[SAM] [DIL], [CAL] [A] (Negative control)

Persistence and degradability No additional information available

Sodium azide (26628-22-8)

Persistence and degradability Not relevant

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no.0247-500-7), and 2-methyl-2H-isothiazol-3-one (EC no. 220-239-6) (3:1) (55965-84-9)

Persistence and degradability Readily biodegradable

Biodegradation >60 % (OECD 301B method)



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12.3. Bioaccumulative potential

SAM **DIL**, **CAL** **A** (Negative control)

Bioaccumulative potential

No additional information available

Sodium azide (26628-22-8)

Log Pow

Not applicable

12.4. Mobility in soil

SAM **DIL**, **CAL** **A** (Negative control)

Ecology - soil

No additional information available

Sodium azide (26628-22-8)

Log Koc

= 2.62. (20°C; (OECD 106 method))

12.5. Results of PBT and vPvB assessment

SAM **DIL**, **CAL** **A** (Negative control)

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

Other adverse effects:

No additional information available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods:

Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

Product/Packaging disposal recommendations:

Dirty containers cannot be handled as normal waste. Disposal must be done according to official regulations.

European List of Waste (LoW) code:

16 05 06* - laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals

HP Code

15 01 02 – plastic packaging

HP12 - Release of an acute toxic gas; waste which releases acute toxic gases (Acute Tox. 1,2 or 3) in contact with water or an acid

HP13 – Sensitising: Waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.



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14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable

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

Contains no substances subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Substance(s) are not subject to Regulation (EC) No. 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC.

VOC content: 0 %

Other information, restriction and prohibition regulation:

Take note of Directive 94/33/EC on the protection of young people at work.

15.1.2. National regulations

No additional information available



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15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

16. OTHER INFORMATION

Indication of changes

Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
2	Labelling	Modified	
3.2	Composition/ information on ingredients	Modified	
9.1	Physical and chemical properties	Modified	
11	Toxicological information	Added	
12	Ecological information	Added	

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by In-land Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No. 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
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
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Regulation (EC) No. 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources:

MSDS of the supplier. IUCLID-Dossier from ECHA.

Department issuing data specification sheet:

R&D department

Contact person:

R&D department



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Full text of H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
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 Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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.
EUH032	Contact with acids liberates very toxic gas.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 (CLP):

Skin Sens. 1 H317 Calculation method

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.