

## **DE7020 ANA Hep Screen ELISA**

## **Flyleaf**

Version number: 2.0 Revision 2023-12-19

## **Bill of materials**

Name of substance	Classification acc. to GHS	Pictograms
CONTROL A		
CONTROL B		
CONTROL C		
SAM DIL 5x		
ENZ CONJ		
SUB TMB		
WASH SOLN 50x		

## **Safety Data Sheet**

according to Regulation (EC) No. 1907/2006 (REACH)

## **CONTROL** A



Version number: 2.0 Revision: 2023-12-07 Replaces version of: 2023-02-17 (1) First version: 2023-02-17

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

#### 1.1 Product identifier

#### Trade name

CONTROL A.

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

Relevant identified uses

In vitro diagnostics

#### 1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Lise-Meitner-Str. 2

24145 Kiel Germany Telephone: +49 (0)431/71922-0 Telefax: +49 (0)431/71922-55 e-mail: info@demeditec.de Website: www.demeditec.de

### e-mail (competent person)

1.4 Emergency telephone number

info@demeditec.de

As above or nearest toxicological information centre.

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### 2.2 Label elements

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

Not required.

#### **Precautionary statements**

**P273** Avoid release to the environment.

**P501** Dispose of contents/container in accordance with

local/regional/national/international regulations.

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) in a concentration of ≥ 0,1%.

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## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

#### Hazardous ingredients acc. to EU regulation

None

## **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### **General notes**

Self-protection of the first aider.

In all cases of doubt, or when symptoms persist, seek medical advice.

## Following inhalation

Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

## Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

This information is not available.

4.3 Indication of any immediate medical attention and special treatment needed None.

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

**Suitable extinguishing media** water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2), Co-ordinate firefighting measures to the fire surroundings

## 5.2 Special hazards arising from the substance or mixture Hazardous

decomposition products: Section 10.

#### **Hazardous combustion products**

nitrogen oxides (NOx)

## 5.3 Advice for firefighters

Non-combustible.

Keep containers cool with water spray.

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

## Special protective equipment for firefighters

Wear self-contained breathing apparatus

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

## For non-emergency personnel

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

## For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

## 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

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#### 6.3 Methods and material for containment and cleaning up

#### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

### Appropriate containment techniques

Use of adsorbent materials.

## Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10. Disposal considerations: see section 13.

## **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

Avoid contact with eyes.

Do not breathe vapour/spray.

### Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

### Specific notes/details

None.

#### Measures to protect the environment Avoid

release to the environment.

#### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

## 7.2 Conditions for safe storage, including any incompatibilities

## Flammability hazards

None.

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### Incompatible substances or mixtures Incompatible

materials: see section 10.

## Protect against external exposure, such as

frost

#### Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

## Ventilation requirements

Provision of sufficient ventilation.

## Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.

#### Packaging compatibilities

Keep only in original container.

## 7.3 Specific end use(s)

No information available.

## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

## Occupational exposure limit values (Workplace Exposure Limits)

This information is not available

## 8.2 Exposure controls

## Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

## Eye/face protection

Wear eye/face protection. (EN 166).

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## **Hand protection**

Protective gloves			
Material	Material thickness	Breakthrough times of the glove material	
no information available	no information available	no information available	

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

#### **Body protection**

Protective clothing against liquid chemicals. (EN 13832, EN 340, EN 14605).

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection. (EN 136, EN 140, EN 14387, EN 143, EN 149).

## **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Colour colourless

**Odour** odourless

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling

range

**Physical state** 

100 °C

liquid

Flammability non-combustible

Lower and upper explosion limit not determined

Flash point not determined

(constituents: not applicable)

Auto-ignition temperature not determined

(constituents: not applicable)

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Decomposition temperature not relevant pH (value) not determined

Kinematic viscosity not determined

Dynamic viscosity not determined

Solubility(ies)

Water solubility

miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure 23 hPa

Density and/or relative density

Density not determined

Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

9.2 Other information

Information with regard to physical hazard

classes hazard classes acc. to GHS (physical hazards):

not relevant

Other safety characteristics there is no additional information

### **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

This material is not reactive under normal ambient conditions.

## 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

#### 10.3 Possibility of hazardous reactions No

known hazardous reactions.

## 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 10.5 Incompatible materials

There is no additional information.

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## 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

## **SECTION 11: Toxicological information**

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

#### Classification procedure

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

### Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### **Acute toxicity**

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Skin corrosion/irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Serious eye damage/eye irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

# Respiratory or skin sensitisation

#### Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

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## Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

## **SECTION 12: Ecological information**

## 12.1 Toxicity

### Aquatic toxicity (acute)

No data available.

#### Aquatic toxicity (chronic)

No data available.

## 12.2 Persistence and degradability

#### **Biodegradation**

No data available.

#### **Persistence**

No data available.

## 12.3 Bioaccumulative potential

No data available.

## 12.4 Mobility in soil

No data available.

## 12.5 Results of PBT and vPvB assessment

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Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

## 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2.

Keep away from drains, surface and ground water.

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

### Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions.

#### **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned	
14.2	UN proper shipping name	-	
14.3	Transport hazard class(es)	-	
14.4	Packing group	-	
14.5	Environmental hazards	-	
14.6	Special precautions for user	-	
14.7	Maritime transport in bulk according to IMO instruments		

### **SECTION 15: Regulatory information**

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII None of

the ingredients are listed.

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List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list None of the ingredients are listed.

#### Seveso Directive Not

assigned.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

Regulation on the marketing and use of explosives precursors None of the ingredients are listed. Regulation on drug precursors None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS) None of the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC) None of the ingredients are listed.

**Regulation on persistent organic pollutants (POP)** None of the ingredients are listed.

#### **National inventories**

Country	Inventory	Status	
AU	AIIC	not all ingredients are listed	
CA	DSL	not all ingredients are listed	
CN	IECSC	all ingredients are listed	
EU	ECSI	all ingredients are listed	
EU	REACH Reg.	not all ingredients are listed	
Country	Inventory	Status	
JP	CSCL-ENCS	not all ingredients are listed	
JP	ISHA-ENCS	not all ingredients are listed	
KR	KECI	not all ingredients are listed	

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MX	INSQ	not all ingredients are listed
NZ	NZIoC	not all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	not all ingredients are listed
VN	NCI	all ingredients are listed

## Legend

AIIC Australian Inventory of Industrial Chemicals

CICR Chemical Inventory and Control Regulation

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSCInventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)

KECI Korea Existing Chemicals Inventory

NCI National Chemical Inventory

NZIoC New Zealand Inventory of Chemicals

PICCSPhilippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH registered

substances Reg.

TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance **CONTROL A**ct

## 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

#### **SECTION 16: Other information**

## Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
1.1	Registration number (REACH): Not relevant (mixture)	-

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1.1	CAS number: Not relevant (mixture)	-
2.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	Classification according to Regulation (EC) No 1272/2008 (CLP): This mixture does not meet the criteria for classification in accordance with Regulation No 1272/ 2008/EC.
2.1	-	Classification: change in the listing (table)
2.1	The most important adverse physicochemical, human health and environmental effects: Spillage and fire water can cause pollution of watercourses.	-
2.2	Labelling according to Regulation (EC) No 1272/ 2008 (CLP)	Labelling according to Regulation (EC) No 1272/ 2008 (CLP): Not required.
2.2	Signal word: Not required.	-
2.2	Pictograms: Not required.	_
2.2	_	Hazard statements: change in the listing (table)
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment:  Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.
3.2	Mixtures	Mixtures: Hazardous ingredients acc. to EU regulation None
3.2	Description of the mixture	-
3.2	-	Hazardous ingredients: change in the listing (table)
3.2	-	Hazardous ingredients: change in the listing (table)

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Section	Former entry (text/value)	Actual entry (text/value)
8.1	Control parameters	Control parameters: Occupational exposure limit values (Workplace Exposure Limits) This information is not available
8.1	-	Occupational exposure limit values (Workplace Exposure Limits): change in the listing (table)
8.1	-	Relevant DNELs of components of the mixture: change in the listing (table)
8.1	<del>-</del>	Relevant PNECs of components of the mixture: change in the listing (table)
8.2	-	Body protection: Protective clothing against liquid chemicals. (EN 13832, EN 340, EN 14605).
15.1	-	Restrictions according to REACH, Annex XVII: change in the listing (table)

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)

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IMDG	International Maritime Dangerous Goods Code
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Abbr.	Descriptions of used abbreviations
Abbr.	Descriptions of used abbreviations  Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods

## Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH).

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

## Responsible for the safety data sheet

Demeditec Diagnostics GmbH Lise-Meitner-Str. 2 24145 Kiel, Germany Telephone: +49 (0)431/71922-0
Telefax: +49 (0)431/71922-55
e-Mail: info@demeditec.de
Website: www.demeditec.de

#### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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#### Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

## CONTROL B



Version number: 2.0 Revision: 2023-12-07 Replaces version of: 2023-02-17 (1) First version: 2023-02-17

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

#### 1.1 Product identifier

Trade name

CONTROL B.

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

Relevant identified uses In vitro diagnostics

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Telephone: +49 (0)431/71922-0
Lise-Meitner-Str. 2 Telefax: +49 (0)431/71922-55
24145 Kiel e-mail: info@demeditec.de

Germany Website: www.demeditec.de

e-mail (competent person) info@demeditec.de

1.4 Emergency telephone number

As above or nearest toxicological information centre.

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

## 2.2 Label elements

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

Not required.

### **Precautionary statements**

**P273** Avoid release to the environment.

**P501** Dispose of contents/container in accordance with

local/regional/national/international regulations.

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

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## **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

#### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

#### Hazardous ingredients acc. to EU regulation

None

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### **General notes**

Self-protection of the first aider.

In all cases of doubt, or when symptoms persist, seek medical advice.

### Following inhalation

Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

## Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

This information is not available.

#### 4.3 Indication of any immediate medical attention and special treatment needed None.

## **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

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**Suitable extinguishing media** water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2), Co-ordinate firefighting measures to the fire surroundings

#### 5.2 Special hazards arising from the substance or mixture Hazardous

decomposition products: Section 10.

#### **Hazardous combustion products**

nitrogen oxides (NOx)

### 5.3 Advice for firefighters

Non-combustible.

Keep containers cool with water spray.

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

#### Special protective equipment for firefighters

Wear self-contained breathing apparatus

#### **SECTION 6: Accidental release measures**

## 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

## For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

## 6.3 Methods and material for containment and cleaning up

### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

#### Appropriate containment techniques

Use of adsorbent materials.

#### Other information relating to spills and releases

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Place in appropriate containers for disposal.

Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

#### **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

Avoid contact with eyes.

Do not breathe vapour/spray.

## Measures to prevent fire as well as aerosol and dust generation Use

local and general ventilation.

#### Specific notes/details

None.

#### Measures to protect the environment Avoid

release to the environment.

## Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

## 7.2 Conditions for safe storage, including any incompatibilities

### Flammability hazards

None.

## Incompatible substances or mixtures Incompatible

materials: see section 10.

## Protect against external exposure, such as

frost

#### Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

## Ventilation requirements

Provision of sufficient ventilation.

### Specific designs for storage rooms or vessels

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Keep container tightly closed and in a well-ventilated place.

## Packaging compatibilities

Keep only in original container.

## 7.3 Specific end use(s)

No information available.

## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

## Occupational exposure limit values (Workplace Exposure Limits)

This information is not available

### 8.2 Exposure controls

## Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

## **Eye/face protection**

Wear eye/face protection. (EN 166).

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## **Hand protection**

Protective gloves				
Material	Material thickness	Breakthrough times of the glove material		
no information available	no information available	no information available		

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

#### **Body protection**

Protective clothing against liquid chemicals. (EN 13832, EN 340, EN 14605).

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection. (EN 136, EN 140, EN 14387, EN 143, EN 149).

## **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state liquid

Colour colourless

**Odour** odourless

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling

range

100 °C

Flammability non-combustible

Lower and upper explosion limit not determined

Flash point not determined

(constituents: not applicable)

Auto-ignition temperature not determined

(constituents: not applicable)

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Decomposition temperature not relevant pH (value) not determined

Kinematic viscosity not determined

Dynamic viscosity not determined

Solubility(ies)

Water solubility

miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure 23 hPa

Density and/or relative density

Density not determined

Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

9.2 Other information

Information with regard to physical hazard

classes hazard classes acc. to GHS (physical hazards):

not relevant

Other safety characteristics there is no additional information

### **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

This material is not reactive under normal ambient conditions.

## 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

#### 10.3 Possibility of hazardous reactions No

known hazardous reactions.

## 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

## 10.5 Incompatible materials

There is no additional information.

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## 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

## **SECTION 11: Toxicological information**

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

#### Classification procedure

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

## Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### **Acute toxicity**

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Skin corrosion/irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Serious eye damage/eye irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

# Respiratory or skin sensitisation

#### Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

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Version number: 2.0 Revision: 2023-12-07

## Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

## **SECTION 12: Ecological information**

## 12.1 Toxicity

#### Aquatic toxicity (acute)

No data available.

#### Aquatic toxicity (chronic)

No data available.

## 12.2 Persistence and degradability

#### **Biodegradation**

No data available.

#### **Persistence**

No data available.

## 12.3 Bioaccumulative potential

No data available.

## 12.4 Mobility in soil

No data available.

## 12.5 Results of PBT and vPvB assessment

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Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

## 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2.

Keep away from drains, surface and ground water.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

### Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions.

#### **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	-
14.3	Transport hazard class(es)	-
14.4	Packing group	-
14.5	Environmental hazards	-
14.6	Special precautions for user	-
14.7	Maritime transport in bulk according to IMO inst	ruments

## **SECTION 15: Regulatory information**

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII None of

the ingredients are listed.

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List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list None of the ingredients are listed.

#### Seveso Directive Not

assigned.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

Regulation on the marketing and use of explosives precursors None of the ingredients are listed. Regulation on drug precursors None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS) None of the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC) None of the ingredients are listed.

**Regulation on persistent organic pollutants (POP)** None of the ingredients are listed.

#### **National inventories**

Country	Inventory	Status		
AU	AIIC	not all ingredients are listed		
CA	DSL	not all ingredients are listed		
CN	IECSC	all ingredients are listed		
EU	ECSI	all ingredients are listed		
EU	REACH Reg.	not all ingredients are listed		
Country	Inventory	Status		
JP	CSCL-ENCS	not all ingredients are listed		
JP	ISHA-ENCS	not all ingredients are listed		
KR	KECI	not all ingredients are listed		

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MX	INSQ	not all ingredients are listed	
NZ	NZIoC	not all ingredients are listed	
PH	PICCS	not all ingredients are listed	
TR	CICR	not all ingredients are listed	
TW	TCSI	all ingredients are listed	
US	TSCA	not all ingredients are listed	
VN	NCI	all ingredients are listed	

## Legend

AIIC Australian Inventory of Industrial Chemicals

CICR Chemical Inventory and Control Regulation

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSCInventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)

KECI Korea Existing Chemicals Inventory

NCI National Chemical Inventory

NZIoC New Zealand Inventory of Chemicals

PICCSPhilippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH registered

substances Reg.

TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance **CONTROL A**ct

## 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

#### **SECTION 16: Other information**

## Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
1.1	Registration number (REACH): Not relevant (mixture)	-

en Page: 12 / 15



Version number: 2.0 Revision: 2023-12-07

1.1	CAS number: Not relevant (mixture)	-
2.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	Classification according to Regulation (EC) No 1272/2008 (CLP): This mixture does not meet the criteria for classification in accordance with Regulation No 1272/ 2008/EC.
2.1	-	Classification: change in the listing (table)
2.1	The most important adverse physicochemical, human health and environmental effects: Spillage and fire water can cause pollution of watercourses.	-
2.2	Labelling according to Regulation (EC) No 1272/ 2008 (CLP)	Labelling according to Regulation (EC) No 1272/ 2008 (CLP): Not required.
2.2	Signal word: Not required.	-
2.2	Pictograms: Not required.	_
2.2	_	Hazard statements: change in the listing (table)
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment:  Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.
3.2	Mixtures	Mixtures: Hazardous ingredients acc. to EU regulation None
3.2	Description of the mixture	-
3.2	-	Hazardous ingredients: change in the listing (table)
3.2	-	Hazardous ingredients: change in the listing (table)

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Section	Former entry (text/value)	Actual entry (text/value)
8.1	Control parameters	Control parameters: Occupational exposure limit values (Workplace Exposure Limits) This information is not available
8.1	-	Occupational exposure limit values (Workplace Exposure Limits): change in the listing (table)
8.1	<del>-</del>	Relevant DNELs of components of the mixture: change in the listing (table)
8.1	<u>-</u>	Relevant PNECs of components of the mixture: change in the listing (table)
8.2	-	Body protection: Protective clothing against liquid chemicals. (EN 13832, EN 340, EN 14605).
15.1	-	Restrictions according to REACH, Annex XVII: change in the listing (table)

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations		
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)		
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures		
DGR	Dangerous Goods Regulations (see IATA/DGR)		
ED	Endocrine disruptor		
EINECS	European Inventory of Existing Commercial Chemical Substances		
ELINCS	European List of Notified Chemical Substances		
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations		
IATA	International Air Transport Association		
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)		

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IMDG	International Maritime Dangerous Goods Code		
NLP	No-Longer Polymer		
PBT	Persistent, Bioaccumulative and Toxic		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals		
Abbr.	Descriptions of used abbreviations		
Abbr.	Descriptions of used abbreviations  Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)		
	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods		

## Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH).

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

## Responsible for the safety data sheet

Demeditec Diagnostics GmbH Lise-Meitner-Str. 2 24145 Kiel, Germany Telephone: +49 (0)431/71922-0
Telefax: +49 (0)431/71922-55
e-Mail: info@demeditec.de
Website: www.demeditec.de

#### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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#### Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

## CONTROL



Version number: 2.0 Revision: 2023-12-07 Replaces version of: 2023-02-17 (1) First version: 2023-02-17

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

#### 1.1 Product identifier

Trade name

CONTROL C.

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

Relevant identified uses In vitro diagnostics

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Telephone: +49 (0)431/71922-0 Lise-Meitner-Str. 2 Telefax: +49 (0)431/71922-55

24145 Kiel e-mail: info@demeditec.de

Germany Website: www.demeditec.de

e-mail (competent person) info@demeditec.de

1.4 Emergency telephone number

As above or nearest toxicological information centre.

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

## 2.2 Label elements

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

Not required.

### **Precautionary statements**

**P273** Avoid release to the environment.

**P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

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## **Control C**



Version number: 2.0 Revision: 2023-12-07

## **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

#### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

#### Hazardous ingredients acc. to EU regulation

None

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### **General notes**

Self-protection of the first aider.

In all cases of doubt, or when symptoms persist, seek medical advice.

### Following inhalation

Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

## Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

This information is not available.

#### 4.3 Indication of any immediate medical attention and special treatment needed None.

## **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

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#### **Control C**



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**Suitable extinguishing media** water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2), Co-ordinate firefighting measures to the fire surroundings

#### 5.2 Special hazards arising from the substance or mixture Hazardous

decomposition products: Section 10.

#### **Hazardous combustion products**

nitrogen oxides (NOx)

### 5.3 Advice for firefighters

Non-combustible.

Keep containers cool with water spray.

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

#### Special protective equipment for firefighters

Wear self-contained breathing apparatus

#### **SECTION 6: Accidental release measures**

## 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

## For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

## 6.3 Methods and material for containment and cleaning up

### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

## Appropriate containment techniques

Use of adsorbent materials.

#### Other information relating to spills and releases

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Place in appropriate containers for disposal.

Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

#### **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

Avoid contact with eyes.

Do not breathe vapour/spray.

## Measures to prevent fire as well as aerosol and dust generation Use

local and general ventilation.

#### Specific notes/details

None.

#### Measures to protect the environment Avoid

release to the environment.

### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Conditions for safe storage, including any incompatibilities

### Flammability hazards

None.

### Incompatible substances or mixtures Incompatible

materials: see section 10.

### Protect against external exposure, such as

frost

#### Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

### Ventilation requirements

Provision of sufficient ventilation.

### Specific designs for storage rooms or vessels

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Keep container tightly closed and in a well-ventilated place.

### Packaging compatibilities

Keep only in original container.

## 7.3 Specific end use(s)

No information available.

# **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

### Occupational exposure limit values (Workplace Exposure Limits)

This information is not available

### 8.2 Exposure controls

## Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

### **Eye/face protection**

Wear eye/face protection. (EN 166).

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### **Hand protection**

Protective gloves			
Material	Material thickness	Breakthrough times of the glove material	
no information available	no information available	no information available	

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

#### **Body protection**

Protective clothing against liquid chemicals. (EN 13832, EN 340, EN 14605).

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection. (EN 136, EN 140, EN 14387, EN 143, EN 149).

### **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

**Colour** colourless

**Odour** odourless

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling

range

**Physical state** 

100 °C

liquid

Flammability non-combustible

Lower and upper explosion limit not determined

Flash point not determined

(constituents: not applicable)

Auto-ignition temperature not determined

(constituents: not applicable)

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Decomposition temperature not relevant pH (value) not determined

Kinematic viscosity not determined

Dynamic viscosity not determined

Solubility(ies)

Water solubility

miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure 23 hPa

Density and/or relative density

Density not determined

Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

9.2 Other information

Information with regard to physical hazard

classes hazard classes acc. to GHS (physical hazards):

not relevant

Other safety characteristics there is no additional information

### **SECTION 10: Stability and reactivity**

# 10.1 Reactivity

This material is not reactive under normal ambient conditions.

### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

#### 10.3 Possibility of hazardous reactions No

known hazardous reactions.

### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 10.5 Incompatible materials

There is no additional information.

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### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

### **SECTION 11: Toxicological information**

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

#### Classification procedure

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

### Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### **Acute toxicity**

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Skin corrosion/irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Serious eye damage/eye irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

# Respiratory or skin sensitisation

#### Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

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Version number: 2.0 Revision: 2023-12-07

### Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

### **SECTION 12: Ecological information**

## 12.1 Toxicity

### Aquatic toxicity (acute)

No data available.

#### Aquatic toxicity (chronic)

No data available.

### 12.2 Persistence and degradability

#### **Biodegradation**

No data available.

#### **Persistence**

No data available.

## 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

## 12.5 Results of PBT and vPvB assessment

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Version number: 2.0 Revision: 2023-12-07

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

#### 12.6 **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) in a concentration of  $\geq 0.1\%$ .

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2.

Keep away from drains, surface and ground water.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions.

#### **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	-
14.3	Transport hazard class(es)	-
14.4	Packing group	-
14.5	Environmental hazards	-
14.6	Special precautions for user	-
14.7	Maritime transport in bulk according to IMO inst	ruments
SECTI	ON 15: Regulatory information	

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII None of

the ingredients are listed.

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Version number: 2.0 Revision: 2023-12-07

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list None of the ingredients are listed.

#### Seveso Directive Not

assigned.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

Regulation on the marketing and use of explosives precursors None of the ingredients are listed. Regulation on drug precursors None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS) None of the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC) None of the ingredients are listed.

**Regulation on persistent organic pollutants (POP)** None of the ingredients are listed.

#### **National inventories**

Country	Inventory	Status
AU	AIIC	not all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	not all ingredients are listed
Country	Inventory	Status
JP	CSCL-ENCS	not all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	not all ingredients are listed

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Version number: 2.0 Revision: 2023-12-07

MX	INSQ	not all ingredients are listed
NZ	NZIoC	not all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	not all ingredients are listed
VN	NCI	all ingredients are listed

### Legend

AIIC Australian Inventory of Industrial Chemicals

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CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSCInventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)

KECI Korea Existing Chemicals Inventory

NCI National Chemical Inventory

NZIoC New Zealand Inventory of Chemicals

PICCSPhilippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH registered

substances Reg.

TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance **CONTROL A**ct

# 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

#### **SECTION 16: Other information**

## Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
1.1	Registration number (REACH): Not relevant (mixture)	-

en Page: 12 / 15



Version number: 2.0 Revision: 2023-12-07

1.1	CAS number: Not relevant (mixture)	-
2.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	Classification according to Regulation (EC) No 1272/2008 (CLP): This mixture does not meet the criteria for classification in accordance with Regulation No 1272/ 2008/EC.
2.1	-	Classification: change in the listing (table)
2.1	The most important adverse physicochemical, human health and environmental effects: Spillage and fire water can cause pollution of watercourses.	-
2.2	Labelling according to Regulation (EC) No 1272/ 2008 (CLP)	Labelling according to Regulation (EC) No 1272/ 2008 (CLP): Not required.
2.2	Signal word: Not required.	-
2.2	Pictograms: Not required.	-
2.2	-	Hazard statements: change in the listing (table)
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment:  Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.
3.2	Mixtures	Mixtures: Hazardous ingredients acc. to EU regulation None
3.2	Description of the mixture	-
3.2	-	Hazardous ingredients: change in the listing (table)
3.2	-	Hazardous ingredients: change in the listing (table)

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Version number: 2.0 Revision: 2023-12-07

Section	Former entry (text/value)	Actual entry (text/value)
8.1	Control parameters	Control parameters: Occupational exposure limit values (Workplace Exposure Limits) This information is not available
8.1	-	Occupational exposure limit values (Workplace Exposure Limits): change in the listing (table)
8.1	-	Relevant DNELs of components of the mixture: change in the listing (table)
8.1	-	Relevant PNECs of components of the mixture: change in the listing (table)
8.2	-	Body protection: Protective clothing against liquid chemicals. (EN 13832, EN 340, EN 14605).
15.1	-	Restrictions according to REACH, Annex XVII: change in the listing (table)

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)

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Version number: 2.0 Revision: 2023-12-07

IMDG	International Maritime Dangerous Goods Code
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Abbr.	Descriptions of used abbreviations
Abbr.	Descriptions of used abbreviations  Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH).

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

### Responsible for the safety data sheet

Demeditec Diagnostics GmbH Lise-Meitner-Str. 2 24145 Kiel, Germany Telephone: +49 (0)431/71922-0 Telefax: +49 (0)431/71922-55 e-Mail: info@demeditec.de Website: www.demeditec.de

### Disclaimer

This information is based upon the present state of our knowledge.

This SDS has been compiled and is solely intended for this product.

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# **Safety Data Sheet**

according to Regulation (EC) No. 1907/2006 (REACH)

### **Diluent**



Version number: 1.0 First version: 2023-02-28

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

#### 1.1 Product identifier

Trade name SAM

DIL 5x.

Registration number (REACH)

Not relevant (mixture)

CAS number

Not relevant (mixture)

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

Relevant identified uses In vitro diagnostics

#### 1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2 24145 Kiel

Germany

Telephone: +49 (0)431/71922-0 Telefax: +49 (0)431/71922-55 e-mail: info@demeditec.de Website: www.demeditec.de

### e-mail (competent person)

1.4 Emergency telephone number

info@demeditec.de

As above or nearest toxicological information centre.

### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

### 2.2 Label elements

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

Not required.

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

#### **Endocrine disrupting properties**

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Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq 0.1\%$ .

### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

### Hazardous ingredients acc. to EU regulation

None

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### **General notes**

In all cases of doubt, or when symptoms persist, seek medical advice.

### Following inhalation

Provide fresh air.

### Following skin contact

Wash with plenty of soap and water.

#### Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

### Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

This information is not available.

### 4.3 Indication of any immediate medical attention and special treatment needed None.

### **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

**Suitable extinguishing media** water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2), Co-ordinate firefighting measures to the fire surroundings

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### 5.2 Special hazards arising from the substance or mixture Hazardous

decomposition products: Section 10.

#### Hazardous combustion products nitrogen

oxides (NOx), hydrogen chloride (HCI)

#### 5.3 Advice for firefighters

Non-combustible.

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

#### Special protective equipment for firefighters

Use suitable breathing apparatus

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

### For non-emergency personnel

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

### For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

#### 6.3 Methods and material for containment and cleaning up

#### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

### Appropriate containment techniques

Use of adsorbent materials.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5.

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Personal protective equipment: see section 8.

Incompatible materials: see section 10. Disposal considerations: see section 13.

### **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

#### Measures to prevent fire as well as aerosol and dust generation Use

local and general ventilation.

#### Specific notes/details

None.

### Measures to protect the environment Avoid

release to the environment.

### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Conditions for safe storage, including any incompatibilities

### Flammability hazards

None.

### Incompatible substances or mixtures Incompatible

materials: see section 10.

### Protect against external exposure, such as

frost

#### Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

#### Ventilation requirements

Provision of sufficient ventilation.

#### Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.

#### Packaging compatibilities

Keep only in original container.

# 7.3 Specific end use(s)

No information available.

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### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

# Occupational exposure limit values (Workplace Exposure Limits)

This information is not available

### 8.2 Exposure controls

#### **Appropriate engineering controls**

Use local and general ventilation.

### Individual protection measures (personal protective equipment)

### Eye/face protection

Wear eye/face protection. (EN 166).

### **Hand protection**

Protective gloves		
Material	Material thickness	Breakthrough times of the glove material
no information available	-	-

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection. (EN 136, EN 140, EN 14387, EN 143, EN 149).

#### **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

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### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state liquid

**Colour** not determined

**Odour** characteristic

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling not determined

range

Flammability non-combustible

Lower and upper explosion limit not determined

Flash point not determined

Auto-ignition temperature not determined

**Decomposition temperature** not relevant

pH (value) not determined

Kinematic viscosity not determined

**Dynamic viscosity** not determined

Solubility(ies)

Water solubility

not miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure not determined

Density and/or relative density

Density not determined

Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

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#### 9.2 Other information

Information with regard to physical hazard

classes

hazard classes acc. to GHS (physical hazards):

not relevant

Other safety characteristics there is no additional information

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

### 10.3 Possibility of hazardous reactions No

known hazardous reactions.

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

#### **SECTION 11: Toxicological information**

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

#### Classification procedure

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

### Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### **Acute toxicity**

Test data are not available for the complete mixture.

#### Skin corrosion/irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Serious eye damage/eye irritation

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Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

# Respiratory or skin sensitisation

#### Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq$  0,1%.

### **SECTION 12: Ecological information**

### 12.1 Toxicity

#### Aquatic toxicity (acute)

No data available.

## Aquatic toxicity (chronic)

No data available.

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### 12.2 Persistence and degradability

### **Biodegradation**

No data available.

#### **Persistence**

No data available.

#### 12.3 Bioaccumulative potential

Test data are not available for the complete mixture.

#### 12.4 Mobility in soil

No data available.

#### 12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions.

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### **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	-
14.3	Transport hazard class(es)	-

14.4 Packing group -

14.5 Environmental hazards -

14.6 Special precautions for user -

14.7 Maritime transport in bulk according to IMO instruments

#### **SECTION 15: Regulatory information**

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII None of

the ingredients are listed.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list None of the ingredients are listed.

Seveso Directive Not

assigned.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

Regulation on the marketing and use of explosives precursors None

of the ingredients are listed. **Regulation on drug precursors** None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS) None of

the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC) None of the

ingredients are listed.

Regulation on persistent organic pollutants (POP) None of

the ingredients are listed.

National inventories

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Country	Inventory	Status	
AU	AIIC	not all ingredients are listed	
CA	DSL	not all ingredients are listed	
CN	IECSC	all ingredients are listed	
EU	ECSI	all ingredients are listed	
EU	REACH Reg.	not all ingredients are listed	
JP	CSCL-ENCS	not all ingredients are listed	
JP	ISHA-ENCS	not all ingredients are listed	
KR	KECI	not all ingredients are listed	
MX	INSQ	not all ingredients are listed	
NZ	NZIoC	not all ingredients are listed	
PH	PICCS	not all ingredients are listed	
TR	CICR	not all ingredients are listed	
TW	TCSI	all ingredients are listed	
US	TSCA	not all ingredients are listed	

### Legend

AIIC Australian Inventory of Industrial Chemicals

CICR Chemical Inventory and Control Regulation

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSCInventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)

KECI Korea Existing Chemicals Inventory

NZIoC New Zealand Inventory of Chemicals

PICCSPhilippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH REACH registered substances Reg.

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TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance **CONTROL** Act

# 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

## **SECTION 16: Other information**

# Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations		
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)		
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)		
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures		
DGR	Dangerous Goods Regulations (see IATA/DGR)		
EINECS	European Inventory of Existing Commercial Chemical Substances		
ELINCS	European List of Notified Chemical Substances		
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations		
IATA	International Air Transport Association		
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)		
IMDG	International Maritime Dangerous Goods Code		
NLP	No-Longer Polymer		
PBT	Persistent, Bioaccumulative and Toxic		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals		
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)		
SVHC	Substance of Very High Concern		

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vPvB	Very Persistent and very Bioaccumulative
------	--

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH).

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

### Responsible for the safety data sheet

Demeditec Diagnostics GmbH Telephone: +49 (0)431/71922-0
Lise-Meitner-Str. 2 Telefax: +49 (0)431/71922-55 e24145 Kiel, Germany Mail: info@demeditec.de Website: www.demeditec.de

#### **Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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# **Safety Data Sheet**

according to Regulation (EC) No. 1907/2006 (REACH)

# Conjugate



Version number: 1.0 First version: 2023-02-28

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

1.1 Product identifier

Trade name ENZ

CONJ.

Registration number (REACH)

Not relevant (mixture)

CAS number

Not relevant (mixture)

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

Relevant identified uses In vitro diagnostics

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2 24145 Kiel

Germany

Telephone: +49 (0)431/71922-0 Telefax: +49 (0)431/71922-55 e-mail: info@demeditec.de

e-mail: info@demeditec.de Website: www.demeditec.de

e-mail (competent person)

1.4 Emergency telephone number

info@demeditec.de

As above or nearest toxicological information centre.

### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

### 2.2 Label elements

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

Not required.

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

#### **Endocrine disrupting properties**

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Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.

### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

### Hazardous ingredients acc. to EU regulation

None

#### **SECTION 4: First aid measures**

### 4.1 Description of first aid measures

#### **General notes**

In all cases of doubt, or when symptoms persist, seek medical advice.

### Following inhalation

Provide fresh air.

#### Following skin contact

Wash with plenty of soap and water.

#### Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

### Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

This information is not available.

### 4.3 Indication of any immediate medical attention and special treatment needed None.

# **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

**Suitable extinguishing media** water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2), Co-ordinate firefighting measures to the fire surroundings

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### 5.2 Special hazards arising from the substance or mixture Hazardous

decomposition products: Section 10.

#### **Hazardous combustion products**

nitrogen oxides (NOx)

#### 5.3 Advice for firefighters

Non-combustible.

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

### Special protective equipment for firefighters

Use suitable breathing apparatus

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

## For non-emergency personnel

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

### For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

#### 6.3 Methods and material for containment and cleaning up

#### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

### Appropriate containment techniques

Use of adsorbent materials.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5.

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Personal protective equipment: see section 8.

Incompatible materials: see section 10. Disposal considerations: see section 13.

### **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

#### Measures to prevent fire as well as aerosol and dust generation Use

local and general ventilation.

#### Specific notes/details

None.

### Measures to protect the environment Avoid

release to the environment.

### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Conditions for safe storage, including any incompatibilities

### Flammability hazards

None.

### Incompatible substances or mixtures Incompatible

materials: see section 10.

### Protect against external exposure, such as

frost

#### Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

#### Ventilation requirements

Provision of sufficient ventilation.

#### Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.

#### Packaging compatibilities

Keep only in original container.

#### 7.3 Specific end use(s)

No information available.

en Page: 4 / 13



### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

### Occupational exposure limit values (Workplace Exposure Limits)

This information is not available

## 8.2 Exposure controls

#### Appropriate engineering controls

Use local and general ventilation.

### Individual protection measures (personal protective equipment)

#### Eye/face protection

Wear eye/face protection. (EN 166).

### **Hand protection**

Protective gloves						
Material	Material thickness	Breakthrough times of the glove material				
no information available	-	-				

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection. (EN 136, EN 140, EN 14387, EN 143, EN 149).

#### **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

en Page: 5 / 13



### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state liquid

**Colour** not determined

**Odour** characteristic

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling

range

not determined

Flammability non-combustible

Lower and upper explosion limit not determined

Flash point not determined

Auto-ignition temperature not determined

**Decomposition temperature** not relevant

pH (value) not determined

Kinematic viscosity not determined

**Dynamic viscosity** not determined

Solubility(ies)

Water solubility

miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure not determined

Density and/or relative density

Density not determined

Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

en Page: 6 / 13



#### 9.2 Other information

Information with regard to physical hazard

classes

hazard classes acc. to GHS (physical hazards):

not relevant

Other safety characteristics

there is no additional information

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

### 10.3 Possibility of hazardous reactions No

known hazardous reactions.

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

#### **SECTION 11: Toxicological information**

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

#### Classification procedure

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

## Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### **Acute toxicity**

Test data are not available for the complete mixture.

#### Skin corrosion/irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Serious eye damage/eye irritation

en Page: 7 / 13



Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

# Respiratory or skin sensitisation

#### Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq$  0,1%.

### **SECTION 12: Ecological information**

### 12.1 Toxicity

#### Aquatic toxicity (acute)

No data available.

## Aquatic toxicity (chronic)

No data available.

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### 12.2 Persistence and degradability

### **Biodegradation**

No data available.

#### **Persistence**

No data available.

### 12.3 Bioaccumulative potential

Test data are not available for the complete mixture.

#### 12.4 Mobility in soil

No data available.

#### 12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.

### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions.

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### **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	-

14.3 Transport hazard class(es) -

14.4 Packing group -

14.5 Environmental hazards -

14.6 Special precautions for user -

14.7 Maritime transport in bulk according to IMO instruments

#### **SECTION 15: Regulatory information**

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Not listed.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list None of the ingredients are listed.

Seveso Directive Not

assigned.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

Regulation on the marketing and use of explosives precursors None

of the ingredients are listed. **Regulation on drug precursors** None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS) None of

the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC) None of the

ingredients are listed.

Regulation on persistent organic pollutants (POP) None of

the ingredients are listed.

**National inventories** 

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Country	Inventory	Status
AU	AIIC	not all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	not all ingredients are listed
EU	ECSI	not all ingredients are listed
EU	REACH Reg.	not all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	not all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	not all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	not all ingredients are listed
US	TSCA	not all ingredients are listed

#### Legend

AIIC Australian Inventory of Industrial Chemicals

CICR Chemical Inventory and Control Regulation

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSCInventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)

KECI Korea Existing Chemicals Inventory

NZIoC New Zealand Inventory of Chemicals

PICCSPhilippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH REACH registered

substances Reg.

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TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance **CONTROL** Act

## 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

## **SECTION 16: Other information**

## Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
IMDG	International Maritime Dangerous Goods Code
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
SVHC	Substance of Very High Concern

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vPvB	Very Persistent and very Bioaccumulative
------	--

## Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH).

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

#### Responsible for the safety data sheet

Demeditec Diagnostics GmbH Telephone: +49 (0)431/71922-0
Lise-Meitner-Str. 2 Telefax: +49 (0)431/71922-55 e24145 Kiel, Germany Mail: info@demeditec.de Website: www.demeditec.de

#### **Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

## тмв



Version number: 1.0 First version: 2023-02-16

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

#### 1.1 Product identifier

Trade name SUB TMB.

Registration number (REACH)

Not relevant (mixture)

CAS number

Not relevant (mixture)

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

Relevant identified uses In vitro diagnostics

For research and development

#### 1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH Telephone: +49 (0)431/71922-0
Lise-Meitner-Str. 2 Telefax: +49 (0)431/71922-55 e24145 Kiel mail: info@demeditec.de
Germany Website: www.demeditec.de

e-mail (competent person) info@demeditec.de

1.4 Emergency telephone number

As above or nearest toxicological information centre.

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### 2.2 Label elements

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

Signal word Not required.
Pictograms Not required.

Supplemental hazard information

**EUH210** Safety data sheet available on request.

#### 2.3 Other hazards

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#### Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

### **Endocrine disrupting properties**

None of the ingredients are listed.

## **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

## **Description of the mixture**

Hazardous ingredients									
Name of substance		Identifier	Wt%	Clas	ssification ac to GHS	C.	Pictog	rams	Notes
2-pyrrolidone		CAS No 616-45-5	1-<3	1 – < 3 Eye Irrit. 2 / H319 Repr. 1B / H360		<u>(!)</u>		-	
		EC No 210-483-1							
	F	REACH Reg. No							
	21	01- 1947547137- xxxx							
Name of substance		Specific (	c Conc. Limits		M-Factors		ATE	Expos	sure route
2-pyrrolidone		Repr. 1B; I	H360: C ≥ 3	%	-		-		-

For full text of H-phrases: see SECTION 16

## **SECTION 4: First aid measures**

## 4.1 Description of first aid measures

#### **General notes**

In all cases of doubt, or when symptoms persist, seek medical advice.

## Following inhalation

Provide fresh air.

## Following skin contact

Wash with plenty of soap and water.

#### Following eye contact

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Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

#### Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

This information is not available.

#### 4.3 Indication of any immediate medical attention and special treatment needed None.

### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

**Suitable extinguishing media** water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2), Co-ordinate firefighting measures to the fire surroundings

#### 5.2 Special hazards arising from the substance or mixture Hazardous

decomposition products: Section 10.

Hazardous combustion products nitrogen oxides (NOx), carbon

monoxide (CO), carbon dioxide (CO2)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

### Special protective equipment for firefighters

Use suitable breathing apparatus

#### **SECTION 6: Accidental release measures**

## 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

## For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

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#### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

#### 6.3 Methods and material for containment and cleaning up

#### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

#### Appropriate containment techniques

Use of adsorbent materials.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10.

Disposal considerations: see section 13.

#### **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

#### Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

Keep away from sources of ignition - No smoking.

#### Specific notes/details

None.

### Measures to protect the environment Avoid

release to the environment.

#### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

#### 7.2 Conditions for safe storage, including any incompatibilities

## Flammability hazards

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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## Incompatible substances or mixtures Incompatible

materials: see section 10.

### Protect against external exposure, such as

frost

#### Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

#### **Ventilation requirements**

Provision of sufficient ventilation.

#### Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.

#### Packaging compatibilities

Keep only in original container.

## 7.3 Specific end use(s)

No information available.

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

## Occupational exposure limit values (Workplace Exposure Limits)

This information is not available

Relevant DNELs of components of the mixture								
Name of substance	CAS No	Endpoint	Threshol d level	Protection goal, route of exposure	Used in	Exposure time		
2-pyrrolidone	616-45-5	DNEL	29.62 mg/ m³	human, inhalatory	worker (industry)	chronic - systemic effects		
2-pyrrolidone	616-45-5	DNEL	4.2 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects		

## Relevant PNECs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
2-pyrrolidone	616-45-5	PNEC	0.5 <sup>mg</sup> /l	freshwater
2-pyrrolidone	616-45-5	PNEC	0.05 <sup>mg</sup> /l	marine water

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2-pyrrolidone	616-45-5	PNEC	10 <sup>mg</sup> /l	sewage treatment plant (STP)
2-pyrrolidone	616-45-5	PNEC	2.17 <sup>mg</sup> /kg	freshwater sediment
2-pyrrolidone	616-45-5	PNEC	0.217 <sup>mg</sup> /kg	marine sediment
2-pyrrolidone	616-45-5	PNEC	0.14 <sup>mg</sup> /kg	soil

## 8.2 Exposure controls

## Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

## Eye/face protection

Wear eye/face protection. (EN 166).

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### **Hand protection**

Protective gloves						
Material	Material thickness	Breakthrough times of the glove material				
no information available	-	-				

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

## Respiratory protection

In case of inadequate ventilation wear respiratory protection. (EN 136, EN 140, EN 14387, EN 143, EN 149).

#### **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

#### **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state liquid

**Colour** colourless to pale yellow

**Odour** characteristic

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling not determined

range (constituents: 250°C cas# 616-45-5)

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point not determined

(constituents: 138°C cas# 616-45-5)

Auto-ignition temperature not determined

(constituents: 395°C cas# 616-45-5)

**Decomposition temperature** not relevant

**pH (value)** 3.5 – 4

Kinematic viscosity not determined

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#### **TMB**



Dynamic viscosity Solubility(ies)

not determined

Water solubility

not miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure not determined

Density and/or relative density

Density 1.011 g/cm³ at 20 °C

Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

9.2 Other information

Information with regard to physical hazard

classes hazard classes acc. to GHS (physical hazards):

not relevant

Other safety characteristics there is no additional information

**SECTION 10: Stability and reactivity** 

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions No

known hazardous reactions.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

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#### **SECTION 11: Toxicological information**

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

#### Classification procedure

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

## Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### **Acute toxicity**

Test data are not available for the complete mixture.

#### Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species	Method	Source
2-pyrrolidone	616-45-5	oral	LD50	6,500 mg/ <sub>kg</sub>	rat	-	Lewis, R.J. Sax's Dangerous Properties of In- dustrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Rein- hold, 1996., p. 2844
2-pyrrolidone	616-45- 5	dermal	LD50	>2,000 mg/ <sub>kg</sub>	rabbit	OECD Guideline 402	ECHA

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

## Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

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# Respiratory or skin sensitisation Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

### Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

None of the ingredients are listed.

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### Aquatic toxicity (acute)

Test data are not available for the complete mixture.

#### Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source

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2- pyrrolidone	616- 45-5	LC50	96 h	4,600 – 10,0 00 <sup>mg</sup> /l	zebra fish (Danio rerio)	OECD Guideline 203	ECHA
2- pyrrolidone	616- 45-5	EC50	48 h	>500 <sup>mg</sup> /l	daphnia magna	EEC directive 79/831 EEC, Annex V, C2	ECHA
2- pyrrolidone	616- 45-5	ErC50	72 h	>500 <sup>mg</sup> /I	algae (Desmodesmus subspicatus)	German standard DIN 38412 Part 9	ECHA

## **Aquatic toxicity (chronic)**

Test data are not available for the complete mixture.

## Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
2- pyrrolidone	616-45- 5	NOEC	96 h	4,640 <sup>mg</sup> /I	zebra fish (Danio rerio)	OECD Guideline 203	ECHA

## 12.2 Persistence and degradability

## Biodegradation

Test data are not available for the complete mixture.

## Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
2- pyrrolidone	616-45-5	DOC removal	98 %	9 d	-	ECHA
2- pyrrolidone	616-45-5	oxygen depletion	73 %	28 d	-	ECHA

## Persistence

No data available.

## 12.3 Bioaccumulative potential

Test data are not available for the complete mixture.

#### Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW

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2-ру	rrolidone	616-45-5	-	-0.71 (25 °C)
				İ

## 12.4 Mobility in soil

No data available.

#### 12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

#### 12.6 Endocrine disrupting properties

None of the ingredients are listed.

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

## Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions.

#### **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	-
14.3	Transport hazard class(es)	-
14.4	Packing group	-
14.5	Environmental hazards	-
14.6	Special precautions for user	-

## 14.7 Maritime transport in bulk according to IMO instruments

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#### **SECTION 15: Regulatory information**

# 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

#### Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	CAS No	Restriction
2-pyrrolidone	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	-	R3

#### Legend

#### R3 1. Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects,2. Articles not complying with paragraph 1 shall not be placed on the market.
- 3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
- can be used as fuel in decorative oil lamps for supply to the general public, and present an aspiration hazard and are labelled with H304.
- 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
- 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling andpackaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
- (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indeliblymarked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil or even sucking the wick of lamps may lead to life-threatening lung damage";
- (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indeliblymarked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage'; (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.';

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list None of the ingredients are listed.

#### Seveso Directive Not

assigned.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

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Regulation on the marketing and use of explosives precursors None of the ingredients are listed. Regulation on drug precursors None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS) None of the ingredients are listed.

### Regulation concerning the export and import of hazardous chemicals (PIC)

Chemicals subject to the international prior informed consent (PIC) procedure (the 'PIC procedure'). Not all ingredients are listed.

## Regulation on persistent organic pollutants (POP) None of

the ingredients are listed.

#### **National inventories**

Country	Inventory	Status
AU	AIIC	not all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	not all ingredients are listed
KR	KECI	not all ingredients are listed
PH	PICCS	not all ingredients are listed
US	TSCA	not all ingredients are listed
EU	ECSI	not all ingredients are listed
EU	REACH Reg.	not all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	not all ingredients are listed

#### Legend

AIIC Australian Inventory of Industrial Chemicals

CICR Chemical Inventory and Control Regulation

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

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#### **TMB**



DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSCInventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

#### Legend

KECI Korea Existing Chemicals Inventory

NZIoC New Zealand Inventory of Chemicals

PICCSPhilippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH registered

substances Reg.

TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance CONTROL Act

## 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

#### **SECTION 16: Other information**

#### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances

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## **TMB**



ELINCS	European List of Notified Chemical Substances		
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control		
Eye Dam.	Seriously damaging to the eye		
Eye Irrit.	Irritant to the eye		
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations		
IATA	International Air Transport Association		
Abbr.	Descriptions of used abbreviations		
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)		
IMDG	International Maritime Dangerous Goods Code		
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008		
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval		
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval		
log KOW	n-Octanol/water		
NLP	No-Longer Polymer		
NOEC	No Observed Effect Concentration		
PBT	Persistent, Bioaccumulative and Toxic		
PNEC	Predicted No-Effect Concentration		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals		
Repr.	Reproductive toxicity		
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)		
SVHC	Substance of Very High Concern		

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vPvB	Very Persistent and very Bioaccumulative
------	--

## Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH).

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

#### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H319	Causes serious eye irritation.
H360	May damage fertility or the unborn child.

## Responsible for the safety data sheet

Demeditec Diagnostics GmbH Lise-Meitner-Str. 2 24145 Kiel, Germany **Disclaimer**  Telephone: +49 (0)431/71922-0 Telefax: +49 (0)431/71922-55 e-Mail:

info@demeditec.de

Website: www.demeditec.de

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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## **Safety Data Sheet**

according to Regulation (EC) No. 1907/2006 (REACH)

#### **WASH**



Version number: 1.0 First version: 2023-02-16

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

#### 1.1 Product identifier

Trade name

WASH SOLN 50x.

Registration number (REACH)Not relevant (mixture)CAS numberNot relevant (mixture)

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

Relevant identified uses In vitro diagnostics

1.3 Details of the supplier of the safety data sheet

Demeditec Diagnostics GmbH

Lise-Meitner-Str. 2

24145 Kiel

Calculate Diagnostics GmbH

Telephone: +49 (0)431/71922-0

Telefax: +49 (0)431/71922-55

e-mail: info@demeditec.de

Website: www.demeditec.de

Germany Website: www.derriedited

e-mail (competent person) info@demeditec.de

1.4 Emergency telephone number

As above or nearest toxicological information centre.

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### 2.2 Label elements

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

Signal word Not required.
Pictograms Not required.

Supplemental hazard information

**EUH210** Safety data sheet available on request.

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

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This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

## **Endocrine disrupting properties**

None of the ingredients are listed.

#### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not relevant (mixture).

#### 3.2 Mixtures

#### **Description of the mixture**

Hazardous ingredie	nts							
Name of substance	Identifier	Wt%	Clas	ssification ac to GHS	C.	Pictogi	rams	Notes
ethylenediaminetet- raacetic acid, disodium salt,	CAS No 6381-92-6	1-<3		te Tox. 4 / H33 DT RE 2 / H37		<u>(!)</u>		-
dihydrate	EC No 205-358-3							
Name of substance	Specific	Conc. Limit	ts	M-Factors		ATE	Expo	sure route
ethylenediaminetet- raacetic acid, disodium salt, dihydrate		-		-	1.	5 <sup>mg</sup> /l/4h	inhala	ation: dust/ mist

For full text of H-phrases: see SECTION 16

#### **SECTION 4: First aid measures**

## 4.1 Description of first aid measures

#### **General notes**

In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following inhalation

Provide fresh air.

#### Following skin contact

Wash with plenty of soap and water.

## Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

#### Following ingestion

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Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

This information is not available.

#### 4.3 Indication of any immediate medical attention and special treatment needed None.

#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

**Suitable extinguishing media** water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO2), Co-ordinate firefighting measures to the fire surroundings

#### 5.2 Special hazards arising from the substance or mixture Hazardous

decomposition products: Section 10.

#### **Hazardous combustion products**

nitrogen oxides (NOx), carbon monoxide (CO), carbon dioxide (CO2), hydrogen chloride (HCI)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

#### Special protective equipment for firefighters

Use suitable breathing apparatus

#### **SECTION 6: Accidental release measures**

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

#### For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

## 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

#### 6.3 Methods and material for containment and cleaning up

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#### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

#### Appropriate containment techniques

Use of adsorbent materials.

### Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10. Disposal considerations: see section 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

#### Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

Keep away from sources of ignition - No smoking.

#### Specific notes/details

None.

#### Measures to protect the environment Avoid

release to the environment.

#### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

#### 7.2 Conditions for safe storage, including any incompatibilities

#### Flammability hazards

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

## Incompatible substances or mixtures Incompatible

materials: see section 10.

#### Protect against external exposure, such as

frost

#### Consideration of other advice

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Keep away from food, drink and animal feeding stuffs.

### Ventilation requirements

Provision of sufficient ventilation.

## Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.

## Packaging compatibilities

Keep only in original container.

#### 7.3 Specific end use(s)

No information available.

## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

#### Occupational exposure limit values (Workplace Exposure Limits)

This information is not available

Relevant DNELs of compo	nents o	f the mixtur	е			
Name of substance	CAS No	Endpoint	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	DNEL	1.5 mg/m³	human, inhalatory	worker (industry	chronic - systemic effects
Relevant DNELs of compo	nents o	f the mixtur	e			
Name of substance	CAS No	Endpoint	Threshol d level	Protection goal, route of exposure	Used ir	Exposure time
ethylenediaminetetraacetic	6381- 92-6	DNEL	1.5 mg/m³	human, inhalatory	worker (industry	chronic -
acid, disodium salt, dihydrate						,
acid,	onents o	f the mixtur	re			,

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ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381-92-6	PNEC	2.5 <sup>mg</sup> /l	freshwater
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381-92-6	PNEC	0.25 <sup>mg</sup> /l	marine water
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381-92-6	PNEC	50 <sup>mg</sup> /l	sewage treatment plant (STP)
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381-92-6	PNEC	1.1 <sup>mg</sup> /kg	soil

## 8.2 Exposure controls

#### Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

## Eye/face protection

Wear eye/face protection. (EN 166).

#### **Hand protection**

Protective gloves		
Material	Material thickness	Breakthrough times of the glove material
no information available	-	-

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

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## Respiratory protection

In case of inadequate ventilation wear respiratory protection. (EN 136, EN 140, EN 14387, EN 143, EN 149).

#### **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state liquid

**Colour** not determined

**Odour** characteristic

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling not determined

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point not determined

Auto-ignition temperature not determined

**Decomposition temperature** not relevant

pH (value) not determined

Kinematic viscosity not determined

**Dynamic viscosity** not determined

Solubility(ies)

Water solubility

miscible in any proportion

Partition coefficient n-octanol/water (log value) not determined

Vapour pressure not determined

Density and/or relative density

Density not determined

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Relative vapour density this information is not available

Particle characteristics not relevant

(liquid)

9.2 Other information

Information with regard to physical hazard

classes

hazard classes acc. to GHS (physical hazards):

not relevant

Other safety characteristics there is no additional information

#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

## 10.3 Possibility of hazardous reactions No

known hazardous reactions.

#### 10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

#### 10.5 Incompatible materials

There is no additional information.

### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

#### **SECTION 11: Toxicological information**

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

#### Classification procedure

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

#### Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

#### **Acute toxicity**

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Test data are not available for the complete mixture.

### Acute toxicity of components of the mixture

Name of substance		CAS No		Exp	osure rout	te	1.5 <sup>mg</sup> /l/4h		
ethylenediaminetet disodium salt,		· 1		,		inhalation: dust/mist			
Name of substance	CAS No	Expo		Endpoint	Value	Species	Meti	hod	Source
ethylenediaminetet- raacetic acid, disodium salt, dihydrate	6381- 92-6	ora	al	LD50	2,800 mg/ <sub>kg</sub>	rat	-		ECHA

#### Skin corrosion/irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Serious eye damage/eye irritation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

# Respiratory or skin sensitisation Skin sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

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## Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

None of the ingredients are listed.

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### Aquatic toxicity (acute)

Test data are not available for the complete mixture.

## Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	LC50	96 h	>116 mg/I	rainbow trout (Oncorhynchus mykiss)	OECD Guideline 203	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	EC50	48 h	>114 mg/I	daphnia magna	OECD Guideline 202	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	ErC50	72 h	>60 mg/I	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA

#### **Aquatic toxicity (chronic)**

Test data are not available for the complete mixture.

#### Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source

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ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	EC50	30 min	>500 mg/I	activated sludge of a predominantly domestic sewage	OECD Guideline 209	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	NOEC	21 d	25 <sup>mg</sup> /I	daphnia magna	OECD Guideline 211	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	NOEC	35 d	≥35.1 <sup>mg</sup> /I	zebra fish (Danio rerio)	OECD Guideline 210	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	NOEC	72 h	48.4 <sup>mg</sup> /l	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	NOEC	3 h	≥640 <sup>mg</sup> /	activated sludge of a predominantly domestic sewage	OECD Guideline 209	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381- 92-6	LOEC	21 d	50 mg/	daphnia magna	OECD Guideline 211	ECHA

## 12.2 Persistence and degradability

## Biodegradation

No data available.

## Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
ethylenediaminetetraacetic acid, disodi- um salt, dihydrate	6381- 92-6	oxygen depletion	23 %	28 d	OECD Guideline 301 D	ECHA

#### Persistence

No data available.

## 12.3 Bioaccumulative potential

Test data are not available for the complete mixture.

## Bioaccumulative potential of components of the mixture

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Name of substance	CAS No	BCF	Log KOW
ethylenediaminetetraacetic acid, disodium salt, di- hydrate	6381-92-6	1.8	-4.3 (pH value: 4.5, 25 °C)

#### 12.4 Mobility in soil

No data available.

#### 12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

#### 12.6 **Endocrine disrupting properties**

None of the ingredients are listed.

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 1

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

14.7

Please consider the relevant national or regional provisions.

## **SECTION 14: Transport information**

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	-
14.3	Transport hazard class(es)	-
14.4	Packing group	-
14.5	Environmental hazards	-
14.6	Special precautions for user	-

# Maritime transport in bulk according to IMO instruments

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#### **SECTION 15: Regulatory information**

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII None of

the ingredients are listed.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list None of the ingredients are listed.

Seveso Directive Not

assigned.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

Regulation on the marketing and use of explosives precursors None of the ingredients are listed. Regulation on drug precursors None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS) None of the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC) None of the ingredients are listed.

Regulation on persistent organic pollutants (POP) None of

the ingredients are listed.

#### **National inventories**

Country	Inventory	Status
AU	AIIC	all ingredients are listed
CA	DSL	all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed

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KR	KECI	all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	all ingredients are listed as "ACTIVE"

#### Legend

AIIC Australian Inventory of Industrial Chemicals

CICR Chemical Inventory and Control Regulation

CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

DSL Domestic Substances List (DSL)

ECSI EC Substance Inventory (EINECS, ELINCS, NLP)

IECSCInventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)

KECI Korea Existing Chemicals Inventory

NZIoC New Zealand Inventory of Chemicals

PICCSPhilippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH registered

substances Reg.

TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance CONTROL Act

#### 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

#### **SECTION 16: Other information**

### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate

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BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven- digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing  50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
Abbr.	Descriptions of used abbreviations
LOEC	Lowest Observed Effect Concentration

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log KOW	n-Octanol/water
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STOT RE	Specific target organ toxicity - repeated exposure
SVHC	Substance of Very High Concern
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH).

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

## List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H332	Harmful if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.

#### Responsible for the safety data sheet

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Website: www.demeditec.de

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## Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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