DE7470 Phospholipid Screen IgG/IgM ELISA

Flyleaf

Version number: 2.0 Revision 2024-01-04

Bill of materials

Name of substance	Classification acc. to GHS	Pictograms
CAL A		
CAL B		
CAL C		
CAL D		
CAL E		
CAL F		
CONTROL 1		
CONTROL 2		
SAM DIL 5x		
ENZ CONJ IgG		
ENZ CONJ IgM		

SUB TMB		

DE7470 Phospholipid Screen IgG/IgM ELISA

Flyleaf

Version number: 2.0 Revision 2024-01-04

Name of substance	Classification acc. to GHS	Pictograms
WASH SOLN 50x		
STOP SOLN		

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

CAL A

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CAL 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) 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.

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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
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.

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

CAL B

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CAL 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
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) 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.

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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
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.

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

CAL C

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CAL 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
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) 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.

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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
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.

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

CAL D

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CAL D.

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) 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.

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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
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.

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

CAL E

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CAL E.

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) 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.

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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)

IECSC Inventory 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

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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
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.

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

CAL F

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CAL F.

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) 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.

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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)

IECSC Inventory 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

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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
Lise-Meitner-Str. 2
24145 Kiel
Germany

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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.

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

CONTROL 1

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CONTROL 1.

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) 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.

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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)

IECSC Inventory 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

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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
Lise-Meitner-Str. 2
24145 Kiel
Germany

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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.

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

CONTROL 2

Version number: 2.0 Revision: 2024-01-03
Replaces version of: 2023-02-28 (1) First version: 2023-02-28

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

1.1 Product identifier

Trade name

CONTROL 2.

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

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Lise-Meitner-Str. 2
24145 Kiel
Germany

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

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%.

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

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

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

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).

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.

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	not determined
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined (constituents: not applicable)
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)
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)

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

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.

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 ≥ 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

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 ≥ 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.

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
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

Country	Inventory	Status
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 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

Indication of changes (revised safety data sheet)

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

Section	Former entry (text/value)	Actual entry (text/value)
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)
2.2	-	Precautionary statements: change in the listing (table)
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)

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).
Section	**Former entry (text/value)**	**Actual entry (text/value)**
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)

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
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

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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.

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) 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.

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 (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

5.2 Special hazards arising from the substance or mixture Hazardous decomposition products: Section 10.

Hazardous combustion products nitrogen oxides (NOx), hydrogen chloride (HCl)

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.

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.

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.

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	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)

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

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 ≥ 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

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.

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

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)

IECSC Inventory 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

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

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
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
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.

Safety Data Sheet

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

Conjugate G

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 IgG.

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) 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.

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 (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

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.

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.

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.

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)

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

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 ≥ 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

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.

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

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)

IECSC Inventory 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

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

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
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
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.

Safety Data Sheet

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

Conjugate M

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 IgM.

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
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e-mail: info@demeditec.de
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.

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 (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

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.

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.

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.

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)

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

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 ≥ 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

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.

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

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)

IECSC Inventory 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

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

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
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
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.

Safety Data Sheet

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

TMB

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
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) 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

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%	Classification acc. to GHS	Pictograms	Notes
2-pyrrolidone	CAS No 616-45-5 EC No 210-483-1 REACH Reg. No 01-211947547137-xxxx	1 – < 3	Eye Irrit. 2 / H319 Repr. 1B / H360		-

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
2-pyrrolidone	Repr. 1B; 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

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.

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.

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	Threshold 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 mg/l	freshwater
2-pyrrolidone	616-45-5	PNEC	0.05 mg/l	marine water

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

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 range	not determined (constituents: 250ºC 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: 138ºC cas# 616-45-5)
Auto-ignition temperature	not determined (constituents: 395ºC cas# 616-45-5)
Decomposition temperature	not relevant
pH (value)	3.5 – 4
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	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.

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/kg	rat	-	Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 2844
2-pyrrolidone	616-45-5	dermal	LD50	>2,000 mg/kg	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.

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

2-pyrrolidone	616-45-5	LC50	96 h	4,600 – 10,000 mg/l	zebra fish (Danio rerio)	OECD Guideline 203	ECHA
2-pyrrolidone	616-45-5	EC50	48 h	>500 mg/l	daphnia magna	EEC directive 79/831 EEC, Annex V, C2	ECHA
2-pyrrolidone	616-45-5	ErC50	72 h	>500 mg/l	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 mg/l	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

2-pyrrolidone	616-45-5	-	-0.71 (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): 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

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 tothe 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.

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)

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 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

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

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.

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 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) 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

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%	Classification acc. to GHS	Pictograms	Notes
ethylenediaminetet-raacetic acid, disodium salt, dihydrate	CAS No 6381-92-6 EC No 205-358-3	1 – < 3	Acute Tox. 4 / H332 STOT RE 2 / H373		-

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
ethylenediaminetet-raacetic acid, disodium salt, dihydrate	-	-	1.5 mg/l/4h	inhalation: 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

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 (HCl)

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

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

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	Threshold 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 components of the mixture

Name of substance	CAS No	Endpoint	Threshold 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 - local effects

Relevant PNECs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment

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

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 range	not determined
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

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

Test data are not available for the complete mixture.

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	ATE
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381-92-6	inhalation: dust/mist	1.5 mg/l/4h

Name of substance	CAS No	Exposure route	Endpoint	Value	Species	Method	Source
ethylenediaminetet-raacetic acid, disodium salt, dihydrate	6381-92-6	oral	LD50	2,800 mg/kg	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.

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/l	rainbow trout (Oncorhynchus mykiss)	OECD Guideline 203	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381-92-6	EC50	48 h	>114 mg/l	daphnia magna	OECD Guideline 202	ECHA
ethylenediaminetetraacetic acid, disodium salt, dihydrate	6381-92-6	ErC50	72 h	>60 mg/l	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

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

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

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.

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

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 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

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

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

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.

Safety Data Sheet

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

STOP

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
STOP SOLN.

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) 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

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%**	**Classification acc. to GHS**	**Pictograms**	**Notes**
phosphoric acid	CAS No 7664-38-2 EC No 231-633-2 Index No 015-011-00-6 REACH Reg. No 01-211948592424-xxxx	3 – < 5	Met. Corr. 1 / H290 Skin Corr. 1B / H314 Eye Dam. 1 / H318		B GHS-HC IOELV

Notes

B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

GHS- Harmonised classification (the classification of the substance corresponds to the entry in the list according to HC: 1272/2008/EC, Annex VI)

IOELV:Substance with a community indicative occupational exposure limit value

Name of substance	**Specific Conc. Limits**	**M-Factors**	**ATE**	**Exposure route**

phosphoric acid	Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Dam. 1; H318: C ≥ 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %	-	-	-

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

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

phosphorus oxides (PxOy)

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.

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.
Never add water to this product.

Specific notes/details

None.

Handling of incompatible substances or mixtures

Do not mix with alkali.

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.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Notation	Source
EU	orthophosphoric acid	7664-382	IOELV	-	1	-	2	-	2000/39/EC
IE	orthophosphoric acid	7664-382	OELV	-	1	-	2	-	S.I. No. 619 of 2001

Notation

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15minute period (unless otherwise specified)

TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

Relevant DNELs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
phosphoric acid	7664-38-2	DNEL	10.7 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
phosphoric acid	7664-38-2	DNEL	1 mg/m³	human, inhalatory	worker (industry)	chronic - local effects

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.

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 (constituents: 296,5ºC cas# 7664-38-2)
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)
Decomposition temperature	not relevant
pH (value)	<1
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)

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

Dangerous/dangerous reactions with Alkalines.

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.

Release of flammable materials with:

light metals (due to the release of hydrogen in an acid/alkaline medium)

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.

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species	Method	Source
phosphoric acid	7664-38-2	oral	LD50	2,600 mg/kg	rat, female	OECD Guideline 423	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.

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
phosphoric acid	7664-38-2	EC50	48 h	>100 mg/l	daphnia magna	OECD Guideline 202	ECHA
phosphoric acid	7664-38-2	ErC50	72 h	>100 mg/l	algae (Desmodesmus subspicatus)	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
phosphoric acid	7664-38-2	EC50	3 h	>1,000 mg/l	activated sludge of a predominantly domestic sewage	OECD Guideline 209	ECHA
phosphoric acid	7664-38-2	NOEC	72 h	100 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
phosphoric acid	7664-38-2	NOEC	3 h	1,000 mg/l	activated sludge of a predominantly domestic sewage	OECD Guideline 209	ECHA

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

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

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

Name	Name acc. to inventory	CAS No	Restriction
phosphoric acid	substances in tattoo inks and permanent make-up	-	R75

Legend

R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a con**Legend** centration equal to or greater than 0,00005 % by weight;

(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitisercategory 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosivecategory 1, 1A, 1B or 1C or skin irritant category 2, or as serious

eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator;

(ii) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present inthe mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g(Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) “Rinse-off products”;

(ii) “Not to be used in products applied on mucous membranes”;

(iii) “Not to be used in eye products”;

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready foruse preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;

(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in aconcentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture “for tattooing purposes” means injection or introduction of themixture into a person’s skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023: (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8); (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classifya substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change thelisting of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that

amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January2022, the mixture is marked with the following information:

(a) the statement “Mixture for use in tattoos or permanent make-up”;

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient

Legend

names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. “Ingredient” means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation

(EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

(d) the additional statement “pH regulator” for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not beused for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, orgenerate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to theuse of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be

exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

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
KR	KECI	all ingredients are listed
MX	INSQ	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)

IECSC Inventory of Existing Chemical Substances Produced or Imported in China

INSQ National Inventory of Chemical Substances

KECI Korea Existing Chemicals Inventory

NZIoC New Zealand Inventory of Chemicals

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH REACH registered substances Reg.

TCSI Taiwan Chemical Substance Inventory

Legend

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
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
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
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
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
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
Abbr.	**Descriptions of used abbreviations**
IOELV	Indicative occupational exposure limit value
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
Met. Corr.	Substance or mixture corrosive to metals
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration

PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
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)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
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
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.

Responsible for the safety data sheet

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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.