Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 16.07.2024 Revision date: 16.07.2024 Version/Replaced version: 11/10

The Safety Data Sheet is usable for:

REF	Name
DEE1000	Histamine ELISA

Single components with dangerous ingredients:

REF	Name	
BA E-0080	Stop Solution	STOP-SOLN
BA E-0085	Acylation Solvent	ACYL-SOLV
BA E-1012	Acylation Reagent	ACYL-REAG
BA E-1040	Enzyme Conjugate	CONJUGATE

Standards and Controls:

BA E-1001	Standard A	STANDARD A
BA E-1002	Standard B	STANDARD B
BA E-1003	Standard C	STANDARD C
BA E-1004	Standard D	STANDARD D
BA E-1005	Standard E	STANDARD E
BA E-1006	Standard F	STANDARD F
BA E-1051	Control 1	CONTROL 1
BA E-1052	Control 2	CONTROL 2

Not listed single components contain no hazardous substances in concentrations to be declared, a labelling is not required.

Stop Solution BA E-0080

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 14.07.2023 Revision date: - Version/Replaced version: 1.0/-

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

1.1. Product identifier

Product form : Mixture

Product name : Stop Solution BA E-0080

UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier/Manufacturer
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel, Germany
Phone +49 431 71922 0
E-mail info@demeditec.de

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency telephone number
Germany	Demeditec Diagnostics GmbH	Lise-Meitner-Str. 2 24145 Kiel, Germany	+49 431 71922 0 (during opening times 8:00-16:30)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Corrosive to metals, Category 1 H290

Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

May be corrosive to metals.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS05

Signal word (CLP) : Warning

Hazard statements (CLP) : H290 - May be corrosive to metals.

Precautionary statements (CLP) : P234 - Keep only in original packaging.
P390 - Absorb spillage to prevent material damage.
P406 - Store in a corrosion resistant container with a resistant inner liner.

Reduced labelling (contents of the package ≤ 125 ml) according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) : -

Signal word (CLP) : -

Hazard statements (CLP) : -

Precautionary statements (CLP) : -

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sulphuric acid	(CAS-No.) 7664-93-9 (EC-No.) 231-639-5 (EC Index-No.) 016-020-00-8	< 5	Met. Corr. 1, H290 Skin Corr. 1A, H314

Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]
Sulphuric acid	(CAS-No.) 7664-93-9 (EC-No.) 231-639-5 (EC Index-No.) 016-020-00-8	(5 ≤ C < 15) Eye Irrit. 2, H319 (5 ≤ C < 15) Skin Irrit. 2, H315 (C ≥ 15) Skin Corr. 1A, H314

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact : Take off immediately all contaminated clothing. Gently wash with plenty of soap and water.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Drink plenty of water as a precaution.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Adapt extinguishing agents to the environment. Carbon dioxide. Foam. Dry extinguishing powder. Water spray.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic gases may be formed. Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate air ventilation. Avoid contact with skin and eyes. Do not breathe vapours/spray.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Absorb spillage to prevent material damage. Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Dispose of in accordance with relevant local regulations.

6.4. Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in corrosive resistant container with a resistant inner liner. Store in original container. Keep container tightly closed. Store in a cool, well-ventilated place. Protect from direct sunlight. Keep out of frost.

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

Incompatible materials : Metals.

7.3. Specific end use(s)

Laboratory reagent, Immunoassays

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sulphuric acid (7664-93-9)		
EU	Local name	Sulphuric acid (mist)
EU	IOEL TWA	0.05 mg/m³
Austria	Local name	Schwefelsäure
Austria	MAK (OEL TWA) (mg/m³)	0.1 E mg/m³
Austria	MAK (OEL STEL) (mg/m³)	0.2 E mg/m³
Belgium	Local name	Acide sulfurique (brume) # Zwavelzuur (nevel)
Belgium	OEL TWA (mg/m³)	0.2 mg/m³
Belgium	Remark	C
Germany	TRGS 900 Local name	Schwefelsäure
Germany	TRGS 900 Occupational Exposure Limit Value (mg/m³)	0.1 E mg/m³
Germany	TRGS 900 Remark	1(I), DFG, EU, Y
Luxembourg	Local name	Acide sulfurique (brume)
Luxembourg	OEL STEL (mg/m³)	0.05 mg/m³
Switzerland	Local name	Schwefelsäure
Switzerland	MAK (mg/m³)	0.1 e mg/m³
Switzerland	KZGW (mg/m³)	0.2 e mg/m³
Switzerland	Notation	$C1^{\#}_{A}$, SSc

8.2. Exposure controls

Appropriate engineering controls:

Provide local exhaust or general room ventilation to minimize vapour concentrations.

Hand protection:

Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Wear safety glasses (EN 166).

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Breathing apparatus with filter type P2.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless
Odour	:	No data available
Melting point/freezing point	:	No data available
Boiling point or initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Lower and upper explosion limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	< 1.0
Kinematic viscosity	:	No data available
Solubility	:	No data available
Partition coefficient n-octanol/water (log value)	:	Not applicable
Vapour pressure	:	No data available
Density and/or relative density	:	No data available
Relative vapour density	:	No data available
Particle size	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

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

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

May be corrosive to metals.

10.4. Conditions to avoid

High temperatures.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases. Strong acids. Metals.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

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

Acute toxicity : Not classified

Based on available data, the classification criteria are not met

Sulphuric acid (7664-93-9)	
LD50 oral rat	2140 mg/kg
LC50 inhalation rat	375 mg/m³

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

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

Respiratory or skin sensitisation : Not classified
Based on available data, the classification criteria are not met

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

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

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

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

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

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

11.2. Information on other hazards

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

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Not classified

Sulphuric acid (7664-93-9)	
LC50 fish	> 16 - < 28 mg/l 96 h, Lepomis macrochirus
EC50 crustacea	> 100 mg/l 48 h, Daphnia magna
EC50 algae	> 100 mg/l 72 h, Desmodesmus subspicatus
NOEC chronic fish	0.31 mg/l 213 d, Salvelinus fontinalis
NOEC chronic crustacea	0.15 mg/l, Tanytarsus dissimilis

12.2. Persistence and degradability

Not required for inorganic substances.

12.3. Bioaccumulative potential

Not required for inorganic substances.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable

14.5. Environmental hazards

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

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 1 - Slightly hazardous to water
WGK Remark : Classification according to AwSV, Annex 1
Storage class (LGK) : LGK 10 - 13
Employment restrictions : Employment prohibitions for the protection of young people at work according to § 22 section 1(6) JArbSchG have to be observed.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

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

Changes compared to the previous version : -

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

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

Full text of H- and EUH-phrases:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

SDS EU (REACH Annex II)

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

Acylation Solvent BA E-0085

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 14.07.2023 Revision date: - Version/Replaced version: 1.0/-

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

1.1. Product identifier

Product form : Mixture

Product name : Acylation Solvent BA E-0085

UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier/Manufacturer
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel, Germany
Phone +49 431 71922 0
E-mail info@demeditec.de

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency telephone number
Germany	Demeditec Diagnostics GmbH	Lise-Meitner-Str. 2 24145 Kiel, Germany	+49 431 71922 0 (during opening times 8:00-16:30)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 2 H225

Serious eye damage/eye irritation, Category 2 H319

Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS02 GHS07

Signal word (CLP) : Danger

Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.
H319 - Causes serious eye irritation.

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed.
P280 - Wear eye protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents/container to an authorised waste collection point.

Reduced labelling (contents of the package ≤ 125 ml) according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS02 GHS07

Signal word (CLP) : Danger

Hazard statements (CLP) : -

Precautionary statements (CLP) : -

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol, ethyl alcohol	(CAS no) 64-17-5 (EC no) 200-578-6 (EC index no) 603-002-00-5 (REACH no) 01-2119457610-43-xxxx	> 99	Flam. Liq. 2, H225 Eye Irrit. 2, H319
Butanone, ethyl methyl ketone	(CAS no) 78-93-3 (EC no) 201-159-0 (EC index no) 606-002-00-3 (REACH no) 01-2119457290-43-xxxx	≤ 1	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 EUH066

Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol, ethyl alcohol	(CAS no) 64-17-5 (EC no) 200-578-6 (EC index no) 603-002-00-5 (REACH no) 01-2119457610-43-xxxx	(C ≥ 50) Eye Irrit. 2, H319

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Make the affected person rest and keep at warm. If breathing stops, give artificial respiration.

First-aid measures after skin contact : Take off immediately all contaminated clothing. Gently wash with plenty of soap and water.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Drink plenty of water as a precaution.

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

Symptoms/effects after eye contact : Causes serious eye irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide. Dry extinguishing powder. Water spray. For a significant fire: Alcohol resistant foam

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.

Explosion hazard : May form flammable/explosive vapour-air mixture.

Hazardous decomposition products in case of fire : Toxic gases may be formed. Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Provide adequate ventilation. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Avoid contact with skin and eyes.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Clean preferably with a detergent - Avoid the use of solvents. Dispose of in accordance with relevant local regulations.

6.4. Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Handle empty containers with care because residual vapours are flammable.

Precautions for safe handling : Provide good ventilation in process area to prevent formation of vapour. Remove all sources of ignition. No open flames. No smoking. Use only non-sparking tools. Take precautionary measures against static discharge. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Take off contaminated clothing and wash it before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Proper grounding procedures to avoid static electricity should be followed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment.

Storage conditions : Store in original container. Keep container tightly closed. Store in a cool, well-ventilated place. Keep in fireproof place. Protect from direct sunlight. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs. Keep away from oxidising agents and strongly alkaline and strongly acidic materials to prevent the possibility of exothermic reaction.

7.3. Specific end use(s)

Laboratory reagent, Immunoassays

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethanol (64-17-5)		
Austria	Local name	Ethanol
Austria	MAK (OEL TWA) (mg/m³)	1900 mg/m³
Austria	MAK (OEL TWA) (ppm)	1000 ppm
Austria	MAK (OEL STEL) (mg/m³)	3800 mg/m³
Austria	MAK (OEL STEL) (ppm)	2000 ppm
Belgium	Local name	Ethanol
Belgium	OEL TWA (mg/m³)	1907 mg/m³
Belgium	OEL TWA (ppm)	1000 ppm
Germany	TRGS 900 Local name	Ethanol
Germany	TRGS 900 Occupational Exposure Limit Value (mg/m³)	200 mg/m³
Germany	TRGS 900 Occupational Exposure Limit Value (ppm)	380 ppm
Germany	TRGS 900 Remark	4(II), DFG,Y
Switzerland	Local name	Ethanol
Switzerland	MAK (mg/m³)	960 mg/m³
Switzerland	MAK (ppm)	500 ppm
Switzerland	KZGW (mg/m³)	1920 mg/m³
Switzerland	KZGW (ppm	1000 ppm

Ethanol (64-17-5)		
Switzerland	Notation (CH)	SSc

Butanone (78-93-3)		
EU	Local name	Butanone
EU	IOELV TWA (mg/m³)	600 mg/m³
EU	IOELV TWA (ppm)	200 ppm
EU	IOELV STEL (mg/m³)	900 mg/m³
EU	IOELV STEL (ppm)	300 ppm
Austria	Local name	Butanon
Austria	MAK (OEL TWA) (mg/m³)	295 mg/m³
Austria	MAK (OEL TWA) (ppm)	100 ppm
Austria	MAK (OEL STEL) (mg/m³)	590 mg/m³
Austria	MAK (OEL STEL) (ppm)	200 ppm
Austria	Remark (AT)	H
Belgium	Local name	2-Butanone # 2-Butanon
Belgium	OEL TWA (mg/m³)	600 mg/m³
Belgium	OEL TWA (ppm)	200 ppm
Belgium	OEL STEL (mg/m³)	900 mg/m³
Belgium	OEL STEL (ppm)	300 ppm
Germany	TRGS 900 Local name	Butanon
Germany	TRGS 900 Occupational Exposure Limit Value (mg/m³)	600 mg/m³
Germany	TRGS 900 Occupational Exposure Limit Value (ppm)	200 ppm
Germany	TRGS 900 Remark	1(I), DFG,EU,H,Y
Germany	TRGS 903 (BGW)	2 mg/l U, b parameter: Butanone (MEK)
Luxembourg	Local name	Butanone
Luxembourg	OEL TWA (mg/m³)	600 mg/m³
Luxembourg	OEL TWA (ppm)	200 ppm
Luxembourg	OEL STEL (mg/m³)	900 mg/m³
Luxembourg	OEL STEL (ppm)	300 ppm
Switzerland	Local name	2-Butanon
Switzerland	MAK (mg/m³)	590 mg/m³
Switzerland	MAK (ppm)	200 ppm
Switzerland	KZGW (mg/m³)	590 mg/m³
Switzerland	KZGW (ppm	200 ppm
Switzerland	Notation (CH)	H, B, SSc
Switzerland	BAT Values	2 mg/l, 27,7 µmol/l, U, b parameter: Butanone (MEK)

Ethanol (64-17-5)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, inhalation	380 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects, inhalation	114 mg/m³
PNEC (Water)	
PNEC aqua (freshwater)	0.96 mg/l
PNEC aqua (marine water)	0.79 mg/l
PNEC aqua (intermittent, freshwater)	2.75 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3.6 mg/kg dwt
PNEC sediment (marine water)	2.9 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.63 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	0.38 g/kg food
PNEC (STP)	
PNEC sewage treatment plant	580 mg/l

Butanone (78-93-3)
DNEL/DMEL (Workers)

Acute - systemic effects, inhalation	900 mg/m³
Long-term - systemic effects, dermal	1161 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	600 mg/m³
DNEL/DMEL (General population)	
Acute - systemic effects, inhalation	450 mg/m³
Long-term - systemic effects,oral	31 mg/kg bodyweight/day
Long-term - systemic effects, dermal	412 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	106 mg/m³

8.2. Exposure controls

Appropriate engineering controls:

Provide local exhaust or general room ventilation to minimize vapour concentrations.

Hand protection:

Wear suitable gloves (EN 374). NBR, 0.425 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Wear safety glasses (EN 166).

Skin and body protection:

Wear suitable protective clothing. Flame retardant antistatic protective clothing.

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Breathing apparatus with filter type ABEK2P3

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless
Odour	:	No data available
Melting point/freezing point	:	No data available
Boiling point or initial boiling point and boiling range	:	No data available
Flammability	:	Highly flammable liquid and vapour
Lower and upper explosion limit	:	No data available
Flash point	:	12 °C (closed cup)
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Kinematic viscosity	:	No data available
Solubility	:	Water: completely miscible
Partition coefficient n-octanol/water (log value)	:	Not applicable
Vapour pressure	:	No data available
Density and/or relative density	:	0.79 g/cm³ (20 °C)
Relative vapour density	:	No data available
Particle size	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties	:	May form flammable/explosive vapour-air mixture.
Oxidising properties	:	No oxidising properties

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour. May form flammable/explosive vapour-air mixture.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. Open flame. Sparks. Ignition sources.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases. Strong acids.

10.6. Hazardous decomposition products

May release flammable gases. In case of fire: Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

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

Acute toxicity : Not classified

Based on available data, the classification criteria are not met

Ethanol (64-17-5)	
LD50 oral rat	10470 mg/kg
LC50 inhalation rat (Vapours)	124.7 mg/l/4 h

Butanone (78-93-3)	
LD50 oral rat	2193 mg/kg
LD50 dermal rabbit	> 10 ml/kg

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified

Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified

Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Based on available data, the classification criteria are not met

11.2. Information on other hazards

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

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Not classified

Ethanol (64-17-5)	
LC50 fish	14200 mg/l 96 h, Pimephales promelas
EC50 daphnia	5012 mg/l 48h,Ceriodaphnia dubia
ErC50 algae	275 mg/l 72 h, Chlorella vulgaris
NOEC fish	250 mg/l 120 h, Danio rerio
NOEC daphnia	9.6 mg/l 10 d, Ceriodaphnia dubia

Butanone (78-93-3)	
LC50 fish	2993 mg/l 96 h, Pimephales promelas
EC50 daphnia	308 mg/l 48 h, Daphnia magna
ErC50 algae	2029 mg/l 72 h, Pseudokirchneriella subcapitata
NOEC algae	566 mg/l 72 h, Raphidocelis subcapitata

12.2. Persistence and degradability

Ethanol (64-17-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	84 %, 20 d

Butanone (78-93-3)	
Persistence and degradability	Readily biodegradable.
Biodegradation	98 %, 28 d

12.3. Bioaccumulative potential

Ethanol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.35 (25 °C)

Butanone (78-93-3)	
Partition coefficient n-octanol/water (Log Pow)	0.3 (40 °C)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

14.5. Environmental hazards

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

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 1 - Slightly hazardous to water
WGK Remark : Classification according to AwSV, Annex 1
Storage class (LGK) : LGK 3 - Flammable liquids
Employment restrictions : Employment prohibitions for the protection of young people at work according to § 22 section 1(6) JArbSchG have to be observed.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

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

Changes compared to the previous version : -

Abbreviations and acronyms:

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

UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis
H225	Highly flammable liquid and vapour
H319	Causes serious eye irritation
H336	May cause drowsiness or dizziness
EUH066	Repeated exposure may cause skin dryness or cracking.

Acylation Reagent BA E-1012

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 14.07.2023 Revision date: - Version/Replaced version: 1.0/-

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

1.1. Product identifier

Product form : Substance

Product name : Acylation Reagent BA E-1012

Substance name : Caprylic acid n-succinimidyl ester

IUPAC name : 2,5-Dioxopyrrolidin-1-yl octanoate

EC-No. : -

CAS-No. : 14464-30-3

Chemical formula : C12H19NO4

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier/Manufacturer
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel, Germany
Phone +49 431 71922 0
E-mail info@demeditec.de

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency telephone number
Germany	Demeditec Diagnostics GmbH	Lise-Meitner-Str. 2 24145 Kiel, Germany	+49 431 71922 0 (during opening times 8:00-16:30)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 4	H302
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	H335

Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P261 - Do not breathe dust.
P280 - Wear protective gloves, protective clothing, eye protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.
P312 - Call a POISON CENTRE or doctor if you feel unwell.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P501 - Dispose of contents/container to an authorised waste collection point.

Reduced labelling (contents of the package ≤ 125 ml) according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning
Hazard statements (CLP) : -
Precautionary statements (CLP) : -

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance name : Caprylic acid n-succinimidyl ester
EC-No. : -
CAS-No. : 14464-30-3

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Caprylic acid n-succinimidyl ester	(CAS-No.) 14464-30-3 (EC-No.) -	100	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a poison center or a doctor if you feel unwell.

First-aid measures after skin contact : Take off immediately all contaminated clothing. Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell. Rinse mouth. Do NOT induce vomiting. Drink plenty of water as a precaution.

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

Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after skin contact : Causes skin irritation.
Symptoms/effects after eye contact : Causes serious eye irritation.
Symptoms/effects after ingestion : Harmful if swallowed.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Adapt extinguishing agents to the environment. Carbon dioxide. Foam. Dry extinguishing powder. Water spray.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Nitrogen oxides.

5.3. Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Stop leak if safe to do so. Ensure adequate air ventilation. Avoid contact with skin and eyes. Do not breathe dust. Avoid dust formation.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up mechanically and collect in suitable container for disposal. Clean contaminated surfaces with an excess of water. Dispose of in accordance with relevant local regulations.

6.4. Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Use only outdoors or in a well-ventilated area. Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust. Wear personal protective equipment.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Take off contaminated clothing and wash it before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container tightly closed. Store in a cool, well-ventilated place. Protect from heat and direct sunlight. Keep out of frost. Store locked up.

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

7.3. Specific end use(s)

Laboratory reagent, Immunoassays

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Provide local exhaust or general room ventilation to minimize dust concentrations.

Hand protection:

Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Wear safety glasses (EN 166).

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Breathing apparatus with filter type P2.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

9.2. Other information

9.2.1. Information with regard to physical hazard classes

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

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

High temperatures.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases. Strong acids.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11: Toxicological information

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

Acute toxicity	:	Harmful if swallowed.
Skin corrosion/irritation	:	Causes skin irritation.
Serious eye damage/irritation	:	Causes serious eye irritation.
Respiratory or skin sensitisation	:	Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	:	Not classified Based on available data, the classification criteria are not met
Carcinogenicity	:	Not classified Based on available data, the classification criteria are not met

Reproductive toxicity	:	Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	:	May cause respiratory irritation.
Specific target organ toxicity (repeated exposure)	:	Not classified Based on available data, the classification criteria are not met
Aspiration hazard	:	Not classified Based on available data, the classification criteria are not met

11.2. Information on other hazards

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

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity	:	Not classified
Chronic aquatic toxicity	:	Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

The substances in this mixture do not meet the PBT- or vPvB criteria of REACH regulation, annex XIII.

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	:	Dispose in a safe manner in accordance with local/national regulations.
Waste treatment methods	:	Do not empty into drains. Dispose of this material and its container in a safe way.
Waste code	:	The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR)	:	Not applicable
UN-No. (IMDG)	:	Not applicable
UN-No. (IATA)	:	Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	:	Not applicable
Proper Shipping Name (IMDG)	:	Not applicable
Proper Shipping Name (IATA)	:	Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	:	Not applicable

IMDG

Transport hazard class(es) (IMDG)	:	Not applicable

IATA

Transport hazard class(es) (IATA)	:	Not applicable

14.4. Packing group

Packing group (ADR)	:	Not applicable
Packing group (IMDG)	:	Not applicable

Packing group (IATA) : Not applicable

14.5. Environmental hazards

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

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 3 - Highly hazardous to water
WGK Remark : Classification according to AwSV, Annex 1
Storage class (LGK) : LGK 10 - 13
Employment restrictions : Employment prohibitions for the protection of young people at work according to § 22 section 1(6) JArbSchG have to be observed.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

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

Changes compared to the previous version : -

Abbreviations and acronyms:

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

STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II)

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

Enzyme Conjugate BA E-1040

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 21.06.2024 Revision date: - Version/Replaced version: 1.0/-

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

1.1. Product identifier

Product form : Mixture

Product name : Enzyme Conjugate BA E-1040

UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier/Manufacturer
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel, Germany
Phone +49 431 71922 0
E-mail info@demeditec.de

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency telephone number
Germany	Demeditec Diagnostics GmbH	Lise-Meitner-Str. 2 24145 Kiel, Germany	+49 431 71922 0 (during opening times 8:00-16:30)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317

Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazardous ingredients : 2-methyl-2H-isothiazol-3-one

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) : P280 - Wear protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P501 - Dispose of contents/container to an authorised waste collection point.

Reduced labelling (contents of the package ≤ 125 ml) according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazardous ingredients : 2-methyl-2H-isothiazol-3-one

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) : P280 - Wear protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P501 - Dispose of contents/container to an authorised waste collection point.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	0.01	Acute Tox. 2 (Inhalation), H330 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410

Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC No) 220-239-6 (EC index No) 613-326-00-9 (REACH No) 01-2120764690-50-xxxx	(C ≥ 0.0015) Skin Sens. 1A, H317

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Make the affected person rest and keep at warm. If breathing stops, give artificial respiration.

First-aid measures after skin contact : Take off immediately all contaminated clothing. Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Drink water as a precaution.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Adapt extinguishing agents to the environment. Carbon dioxide. Foam. Dry extinguishing powder. Water spray.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Sulphur oxides. Nitrogen oxides.

5.3. Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Stop leak if safe to do so. Provide adequate ventilation. Avoid contact with skin and eyes. Do not breathe vapours/spray.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Dispose of in accordance with relevant local regulations.

6.4. Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.

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

7.2. Conditions for safe storage, including any incompatibilities

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

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

7.3. Specific end use(s)

Laboratory reagent, Immunoassays.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

2-methyl-2H-isothiazol-3-one (2682-20-4)	
DNEL/DMEL (Workers)	
Long-term - local effects, inhalation	0.021 mg/m³
Acute - local effects, inhalation	0.043 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	0.027 mg/kg bodyweight/day
Acute - systemic effects, oral	0.053 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.021 mg/m³
Acute - local effects, inhalation	0.043 mg/m³
PNEC (Water)	
PNEC aqua (freshwater)	3.39 µg/l
PNEC aqua (marine water)	3.39 µg/l
PNEC aqua (intermittent, freshwater)	3.39 µg/l
PNEC aqua (intermittent, marine water)	3.39 µg/l
PNEC (Soil)	
PNEC soil	0.047 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	0.23 mg/l

8.2. Exposure controls

Appropriate engineering controls:

Provide local exhaust or general room ventilation to minimize vapour concentrations.

Hand protection:

Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm, Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Wear safety glasses (EN 166).

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Breathing apparatus with filter type A.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

9.2. Other information

9.2.1. Information with regard to physical hazard classes

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

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

High temperatures.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases. Strong acids.

10.6. Hazardous decomposition products

No hazardous decomposition products known. In case of fire: Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Sulphur oxides. Nitrogen oxides.

SECTION 11: Toxicological information

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

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

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

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

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

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

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

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

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

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

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

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disruption for human health : The mixture has no endocrine disrupting properties.

11.2.2. Other information

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

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Not classified

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

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

2-methyl-2H-isothiazol-3-one (2682-20-4)	
Partition coefficient n-octanol/water (Log Pow)	-0.486 (20 °C)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

Endocrine disruption for the environment : The mixture has no endocrine disrupting properties.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Water hazard class (WGK)	:	WGK 1 - Slightly hazardous to water
WGK Remark	:	Classification according to AwSV, Annex 1
Storage class (LGK)	:	LGK 10 - 13
Employment restrictions	:	Employment prohibitions for the protection of young people at work according to § 22 section 1(6) JArbSchG have to be observed.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Data sources	:	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Changes compared to the previous version	:	-

Abbreviations and acronyms:

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

Full text of H- and EUH-phrases:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/ irritation, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, Category 1A
H301	Toxic if swallowed
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction.

H318	Causes serious eye damage
H330	Fatal if inhaled
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II)

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

Standards and Controls BA E-1001, BA E-1002, BA E-1003, BA E-1004, BA E-1005, BA E-1006, BA E-1051 and BA E-1052

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 14.07.2023 Revision date: - Version/Replaced version: 1.0/-

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

1.1. Product identifier

Product form : Mixture

Product name : Standards and Controls BA E-1001, BA E-1002, BA E-1003, BA E-1004, BA E-1005, BA E-1006, BA E-1051 and BA E-1052

UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Laboratory reagent, Immunoassays
Use by professionals.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier/Manufacturer
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel, Germany
Phone +49 431 71922 0
E-mail info@demeditec.de

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency telephone number
Germany	Demeditec Diagnostics GmbH	Lise-Meitner-Str. 2 24145 Kiel, Germany	+49 431 71922 0 (during opening times 8:00-16:30)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Corrosive to metals, Category 1 H290

Full text of H-statements: see section 16

Adverse physicochemical, human health and environmental effects

May be corrosive to metals. Causes severe skin burns and eye damage.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS05

Signal word (CLP) : Warning

Hazard statements (CLP) : H290 - May be corrosive to metals.

Precautionary statements (CLP) : P234 - Keep only in original packaging.
P390 - Absorb spillage to prevent material damage.
P406 - Store in a corrosion resistant container with a resistant inner liner.

Reduced labelling (contents of the package ≤ 125 ml) according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) : -

Signal word (CLP) : -

Hazard statements (CLP) : -

Precautionary statements (CLP) : -

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
hydrochloric acid … %	(EC-No) 231-595-7 (EC Index-No) 017-002-01-X	< 1	Met. Corr. 1, H290 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335

Name	Product identifier	Specific concentration limits according to Regulation (EC) No. 1272/2008 [CLP]
hydrochloric acid … %	(EC-No) 231-595-7 (EC Index-No) 017-002-01-X	(10 ≤ C < 25) Skin Irrit. 2, H315 (10 ≤ C < 25) Eye Irrit. 2, H319 (10 ≤ C ≤ 100) STOT SE 3, H335 (25 ≤ C ≤ 100) Skin Corr. 1B, H314

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact : Take off immediately all contaminated clothing. Gently wash with plenty of soap and water.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Drink plenty of water as a precaution.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Adapt extinguishing agents to the environment. Carbon dioxide. Foam. Dry extinguishing powder. Water spray.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Hydrogen chloride. Chlorine.

5.3. Advice for firefighters

Firefighting instructions : Prevent firefighting water from entering the environment. Use water spray or fog for cooling exposed containers.

Protection during firefighting : Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate air ventilation. Avoid contact with skin and eyes. Do not breathe vapours/spray.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Absorb spillage to prevent material damage. Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Dispose of in accordance with relevant local regulations.

6.4. Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe vapour/aerosol.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in corrosive resistant container with a resistant inner liner. Store in original container. Keep container tightly closed. Store in a cool, well-ventilated place. Protect from direct sunlight. Keep out of frost.

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

Incompatible materials : Metals.

7.3. Specific end use(s)

Laboratory reagent, Immunoassays

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Hydrochloric acid … % (EC 231-595-7)		
EU	Local name	Hydrogen chloride
EU	IOELV TWA (mg/m³)	8 mg/m³
EU	IOELV TWA (ppm)	5 ppm
EU	IOELV STEL (mg/m³)	15 mg/m³
EU	IOELV STEL (ppm)	10 ppm
Austria	Local name	Chlorwasserstoff
Austria	MAK (OEL TWA) (mg/m³)	8 mg/m³
Austria	MAK (OEL TWA) (ppm)	5 ppm
Austria	MAK (OEL STEL) (mg/m³)	15 mg/m³
Austria	MAK (OEL STEL) (ppm)	10 ppm
Belgium	Local name	Hydrogène (chlorure d') # Waterstofchloride
Belgium	OEL TWA (mg/m³)	8 mg/m³
Belgium	OEL TWA (ppm)	5 ppm
Belgium	OEL STEL (mg/m³)	15 mg/m³
Belgium	OEL STEL (ppm)	10 ppm
Germany	TRGS 900 Local name	Hydrogenchlorid
Germany	TRGS 900 Occupational Exposure Limit Value (mg/m³)	3 mg/m³
Germany	TRGS 900 Occupational Exposure Limit Value (ppm)	2 ppm
Germany	TRGS 900 Remark	2(I), DFG, EU, Y
Luxembourg	Local name	Chlorure d'hydrogène
Luxembourg	OEL TWA (mg/m³)	8 mg/m³
Luxembourg	OEL TWA (ppm)	5 ppm
Luxembourg	OEL STEL (mg/m³)	15 mg/m³
Luxembourg	OEL STEL (ppm)	10 ppm
Switzerland	Local name	Acide chlorhydrique / Chlorwasserstoff [Salzsäure]
Switzerland	MAK (mg/m³)	3 mg/m³

Hydrochloric acid … % (EC 231-595-7)		
Switzerland	MAK (ppm)	2 ppm
Switzerland	KZGW (mg/m³)	6 mg/m³
Switzerland	KZGW (ppm)	4 ppm
Switzerland	Notation	SSC

Hydrochloric acid … % (EC 231-595-7)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	15 mg/m³
Long-term - local effects, inhalation	8 mg/m³
DNEL/DMEL (General population)	
Acute - local effects, inhalation	15 mg/m³
Long-term - local effects, inhalation	8 mg/m³

8.2. Exposure controls

Appropriate engineering controls:

Provide local exhaust or general room ventilation to minimize vapour concentrations.

Hand protection:

Wear suitable gloves (EN 374). Nitrile rubber, 0.35 mm. Butyl rubber, 0.5 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Wear safety glasses (EN 166).

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Breathing apparatus with filter type P2.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless
Odour	:	No data available
Melting point/freezing point	:	No data available
Boiling point or initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Lower and upper explosion limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	1.0 - 1.3
Kinematic viscosity	:	No data available
Solubility	:	No data available
Partition coefficient n-octanol/water (log value)	:	Not applicable
Vapour pressure	:	No data available
Density and/or relative density	:	No data available
Relative vapour density	:	No data available
Particle size	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties : No explosive properties

Oxidising properties : No oxidising properties

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

May be corrosive to metals.

10.4. Conditions to avoid

High temperatures.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases. Strong acids. Metals.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Hydrogen chloride. Chlorine.

SECTION 11: Toxicological information

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

Acute toxicity : Not classified

Based on available data, the classification criteria are not met

Hydrochloric acid … % (EC 231-595-7)	
LC50 inhalation rat	7051 mg/m³ 30 min

Skin corrosion/irritation : Not classified

Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified

Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Based on available data, the classification criteria are not met

11.2. Information on other hazards

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

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Not classified

Hydrochloric acid … % (EC 231-595-7)	
LC50 fish	pH 3.25 – 3.5 96 h, Lepomis macrochirus
EC50 crustacea	pH 4.92 48 h, Daphnia magna
EC50 algae	pH 4.7 72 h, Chlorella vulgaris

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential
No additional information available

12.4. Mobility in soil
No additional information available

12.5. Results of PBT and vPvB assessment
Not fulfilling Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) criteria.

12.6. Endocrine disrupting properties
No additional information available

12.7. Other adverse effects
No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Do not empty into drains. Dispose of this material and its container in a safe way.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number
UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

14.2. UN proper shipping name
Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

14.3. Transport hazard class(es)
ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

14.4. Packing group
Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

14.5. Environmental hazards
Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Water hazard class (WGK)	:	WGK 1 - Slightly hazardous to water
WGK Remark	:	Classification according to AwSV, Annex 1
Storage class (LGK)	:	LGK 10 - 13
Employment restrictions	:	Employment prohibitions for the protection of young people at work according to § 22 section 1(6) JArbSchG have to be observed.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Data sources	:	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Changes compared to the previous version	:	-

Abbreviations and acronyms:

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

vPvB	Very Persistent and Very Bioaccumulative

Full text of H- and EUH-phrases:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II)

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