

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

Page 1

Trade name: ELISA Kits (see below listing)

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards) ENZ CONJ Conjugate

Date of issue: 05/07/2019

Revision date: 05/07/2019 Supersedes: 09/01/2019

Version: 9.00

## 1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAK-**ING**

1.1. Product Identifier

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards) Trade name:

**ENZ CONJ Conjugate** 

Products:

Product name	CatNo.
Anaplasma vet ELISA	DEANAVT0850
Babesia vet ELISA	DEBABVT0890
Borrelia vet ELISA	DEBORVT0040
Brucella vet ELISA	DEBRUVT0050
Coxiella Phase 1 vet ELISA	DECOX1VT0600
Coxiella Phase 2 vet ELISA	DECOX2VT0600
Coxiella (bovine) vet ELISA	DECOXVT0600
Dirofilaria Antigen vet ELISA	DEDIRVT4760
Echinococcus vet ELISA	DEECHVT0130
Ehrlichia vet ELISA	DEEHRVT0930
Feline Leukemia Virus (FeLV) Antigen ELISA	DEFELVT4800
Feline Corona Virus (FCoVFIP) ELISA	DEFIPVT0870
Feline Immunodeficiency Virus (FIV) ELISA	DEFIVVT0750)
Feline Parvovirus (FPV) ELISA	DEFPVVT0910
Leishmania vet ELISA	DE0310
Leptospira vet ELISA	DELEPVT0660
Canine Distemper Virus (CDV) ELISA	DEMEAVT0330
Canine Parvovirus (CPV) ELISA	DEPARVT0370
Pasteurella multocida Toxin Antibody vet ELISA	DEPASVT0960
TBE-FSME vet ELISA	DETICVT0440
Toxocara vet ELISA	DETOCVT0450
Toxoplasma vet ELISA	DETOXVT0460
Trichinella vet ELISA	DETRIVT0480



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

Page 2

Trade name: ELISA		
CAL B (Cut-Off con	trol), CAL C (Po	sitive control),
CAL A – E (Standa	rds) ENZ CON	J Conjugate

Date of issue: 05/07/2019

Revision date: 05/07/2019 Supersedes: 09/01/2019

Version: 9.00

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

## 1.2.1. Relevant identified uses

Use of substance/mixture: in vitro diagnostics

## 1.2.2. Uses advised against

No additional information available

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

**Supplier** 

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

## 1.4. Emergency telephone number

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



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

Page 3

Trade name: ELISA Kits (see below listing)

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards) ENZ CONJ Conjugate

Revision date: 05/07/2019 Supersedes: 09/01/2019

Date of issue: 05/07/2019

Version: 9.00

### 2. HAZARDS IDENTIFICATION

## 2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1

Full text of H statements: see section 16

## Adverse physicochemical, human health and environmental effect

May cause an allergic skin reaction.

### 2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) Warning

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

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

P261: Avoid breathing mist, vapours, spray.

P280: Wear protective gloves.

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

P333+P313: If skin irritation or rash occurs: Get medical advice/atten-

tion.

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

#### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Comments: Solvent mixture with additives

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



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

Page 4

Trade name: ELISA Kits (see below listing)

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

CAL A – E (Standards) ENZ CONJ Conjugate

Date of issue: 05/07/2019

Revision date: 05/07/2019 Supersedes: 09/01/2019

Version: 9.00

**Specific concentration limits:** 

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

Full text of H-statements: see section 16

### 4. FIRST AID MEASURES

## 4.1. Description of the first aid measures

First-aid measures general: In all cases of doubt, or when symptoms persist, seek medical

attention.

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for

breathing.

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

ter. Cover wounds with sterile bandage. Get medical advice if skin irritation persists. If skin irritation or rash occurs: Get

medical advice/ attention

First-aid measures after eye contact: Rinse eyes with water as a precaution. Remove contact

lenses, if present and easy to do. Continue rinsing. In case of contact with eyes, rinse immediately with plenty of water and

seek medical advice.

First-aid measures after ingestion: Rinse mouth out with water. Drink plenty of water. Do NOT

induce vomiting. Call a doctor. Call a poison center or a doctor

if you feel unwell.

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

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

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

Treat symptomatically.

## 5. FIREFIGHTING MEASURES

## 5.1. Extinguishing media

Suitable extinguishing media: Not combustible. Use extinguishing media appropriate for sur-

rounding fire. Water spray. Dry powder. Foam Carbon dioxide.

Unsuitable extinguishing media: Strong water jet.

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

Hazardous decomposition products

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

5.3. Advice for firefighters

Protection during firefighting: Do not attempt to take action without suitable protective

equipment. Self-contained breathing apparatus. Complete

protective clothing.

Other information: Do not allow run-off from the fire-fighting to enter drains or

water courses. Disposal must be done according to official

regulations.

## de medi iec

## SAFETY DATA SHEET

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

Page 5

Trade name: ELISA Kits (see below listing)

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards) ENZ CONJ Conjugate

Revision date: 05/07/2019 Supersedes: 09/01/2019

Date of issue: 05/07/2019

Version: 9.00

## 6. ACCIDENTAL RELEASE MEASURES

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

## 6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see sec-

tion 8.

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

Avoid breathing mist, vapours, spray.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equip-

ment. For further information refer to section 8: "Exposure

controls/personal protection".

## 6.2. Environmental precautions

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

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

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw

dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Wash away remainder with plenty of water.

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

### 6.4. Reference to other sections

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

## 7. HANDLING AND STORAGE

## 7.1. Precautions for safe handling

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

skin and eyes. Wear personal protective equipment. Avoid

breathing mist, vapours, spray.

Hygiene measures: Contaminated work clothing should not be allowed out of

workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash

hands after handling the product.

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

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

Information about storage in one

common storage facility: Keep away from food, drink and animal feeding stuffs.

## 7.3. Specific end use(s)

In vitro diagnostics.

## de medi iec

## SAFETY DATA SHEET

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

Page 6

Trade name: ELISA Kits (see below listing)

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards) ENZ CONJ Conjugate

Revision date: 05/07/2019

Date of issue: 05/07/2019

Supersedes: 09/01/2019 Version: 9.00

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## 8.1. Control parameters

2-methyl-2H-isothiazol-3-one (2682-2	20-4)
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	0.043 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.021 mg/m <sup>3</sup>
DNEL/DMEL (General population)	N2 170
Acute - systemic effects, oral	0.053 mg/kg bodyweight
Acute - local effects, inhalation	0.043 mg/m³
Long-term - systemic effects,oral	0.027 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.021 mg/m³
PNEC (Water)	20
PNEC aqua (freshwater)	3.39 µg/L
PNEC aqua (marine water)	3.39 µg/L
PNEC aqua (intermittent, freshwater)	3.39 µg/L
2-methyl-2H-isothiazol-3-one (2682-2	0-4)
PNEC aqua (intermittent, marine water)	3.39 µg/L
PNEC (Soil)	
PNEC soil	0.047 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	0.23 mg/l

#### 8.2. Exposure controls

## **Appropriate engineering controls:**

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

## Hand protection:

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

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

## Eye protection:

Chemical goggles. EN 166

## Skin and body protection:

Wear suitable protective clothing. EN 340. EN 13034

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

Page 7

Trade name: ELISA Kits (see below listing) CAL B (Cut-Off control), CAL C (Positive control),

CAL A - E (Standards) ENZ CONJ Conjugate

Date of issue: 05/07/2019

Revision date: 05/07/2019 Supersedes: 09/01/2019

Version: 9.00

## Respiratory protection:

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

## **Environmental exposure controls:**

Avoid release to the environment.

#### Other information

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

### PHYSICAL AND CHEMICAL PROPERTIES

## 9.1. Information on basic physical and chemical properties

Physical state: liquid Colour: yellow Odour: odourless

Odour threshold: no data available.  $6.3 - 7.5 (20^{\circ}C)$ pH: Relative evaporation rate (butylacetate = 1) no data available Melting point: not applicable Freezing point: no data available Boiling point: no data available Flash point: no data available Auto-ignition temperature: no data available Decomposition temperature: no data available Flammability (solid, gas): not applicable Vapour pressure: no data available Relative vapour density at 20°C: no data available Relative density: no data available Solubility: water: miscible Log Pow: no data available Viscosity, kinematic: no data available Viscosity, dynamic: no data available

Oxidising properties: non oxidizing **Explosive limits:** no data available

## 10. STABILITY AND REACTIVITY

## 10.1. Reactivity

Explosive properties:

No additional information available.

## 10.2. Chemical stability

No decomposition if stored normally.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

heat

product is not explosive



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

Page 8

Trade name: ELISA Kits (see below listing)	
CAL B (Cut-Off control), CAL C (Positive control),	
CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards) ENZ CONJ Conjugate	

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

Date of issue: 05/07/2019

## 10.5. Incompatible materials

No additional information available.

## 10.6 Hazardous decomposition products

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

## 11. TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

Acute toxicity (oral): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (dermal): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (inhalation): not classified (Based on available data, the classification crite-

ria are not met)

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

Skin corrosion/irritation: not classified (Based on available data, the classification crite-

> ria are not met) ph: 6.3 - 7.5 (20°C)

Additional information: Repeated or prolonged skin contact may cause irritation Serious eye damage/irritation:

not classified (Based on available data, the classification crite-

ria are not met) ph: 6.3 – 7.5 (20°C)

Additional information: Slight eye irritant upon direct contact Respiratory or skin sensitisation: May cause an allergic reaction

Germ cell mutagenicity: not classified (Based on available data, the classification crite-

ria are not met)

Carcinogenicity: not classified (Based on available data, the classification crite-

ria are not met)

Reproductive toxicity: not classified (Based on available data, the classification crite-

ria are not met)

STOT-single exposure: not classified (Based on available data, the classification crite-

ria are not met)

STOT-repeated exposure: not classified (Based on available data, the classification crite-

ria are not met)

not classified (Based on available data, the classification crite-Aspiration hazard:

ria are not met)



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

Page 9

Trade name: ELISA Kits (see below listing)

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards) ENZ CONJ Conjugate

Date of issue: 05/07/2019

Revision date: 05/07/2019 Supersedes: 09/01/2019

Version: 9.00

## 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Acute aquatic toxicity: not classified (Based on available data, the classification crite-

ria are not met)

Chronic aquatic toxicity: not classified (Based on available data, the classification crite-

ria are not met)

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

12.2. Persistence and degradability

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards), ENZ CONJ Conjugate	
Persistence and degradability	No additional information available

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

12.3. Bioaccumulative potential

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards), ENZ CONJ Conjugate		
Log Pow	Not applicable	
Bioaccumulative potential	No additional information available	

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

12.4. Mobility in soil

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards), ENZ CONJ Conjugate		
Ecology - soil	No additional information available	

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

## 12.5. Results of PBT and vPvB assessment

CAL B (Cut-Off control), CAL C (Positive control), CAL A – E (Standards), ENZ CONJ Conjugate
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## 12.6. Other adverse effects

Other adverse effects: No additional information available.

## de medi a

## SAFETY DATA SHEET

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

Page 10

Trade name: ELISA Kits (see below listing)

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

CAL A – E (Standards) ENZ CONJ Conjugate

Date of issue: 05/07/2019

Revision date: 05/07/2019 Supersedes: 09/01/2019

Version: 9.00

## 13. DISPOSAL CONSIDERATIONS

## 13.1. Waste treatment methods

Waste treatment methods: Disposal must be done according to official regulations. Euro-

pean waste catalogue. Do not dispose of with domestic waste.

Do not discharge into drains or the environment.

Product/Packaging disposal

recommendations:

Dirty containers cannot be handled as normal waste. Disposal

must be done according to official regulations.

European List of Waste (LoW) code: 16 05 06\* - laboratory chemicals consisting of or containing

dangerous substances including mixtures of laboratory chemi-

cals

15 01 02 - plastic packaging

HP Code: HP13 – "Sensitising": Waste which contains one or more sub-

stances known to cause sensitising effects to the skin or the

respiratory organs.

### 14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN number	Not	Not	Not	Not	Not
14.1. ON Humber	applicable	applicable	applicable	applicable	applicable
14.2. UN proper shipping name	Not	Not	Not	Not	Not
14.2. ON proper shipping hame	applicable	applicable	applicable	applicable	applicable
14.3. Transport hazard class(es)	Not	Not	Not	Not	Not
	applicable	applicable	applicable	applicable	applicable
14.4 Packing group	Not	Not	Not	Not	Not
14.4 Packing group	applicable	applicable	applicable	applicable	applicable
14.5. Environmental hazards	Not	Not	Not	Not	Not
14.5. Environmental hazards	applicable	applicable	applicable	applicable	applicable
No supplementary information available					

## 14.6. Special precautions for user

- Overland transport
   Not applicable
- Transport by sea Not applicable
- Air transport Not applicable
- Inland waterway transport Not applicable
- Rail transport Not applicable

## 14.7. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable



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

Page 11

Trade name: ELISA Kits (see below listing)

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

CAL A – E (Standards) ENZ CONJ Conjugate

Revision date: 05/07/2019 Supersedes: 09/01/2019

Date of issue: 05/07/2019

Version: 9.00

## 15. REGULATORY INFORMATION

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

## 15.1.1. EU-Regulations

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

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

CAL B, CAL C

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances

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

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

Other information, restriction and prohibition regulation:

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

#### 15.1.2. National regulations

No additional information available

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.



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

Page 12

Trade name: ELISA Kits (see below listing)

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

CAL A – E (Standards) ENZ CONJ Conjugate

Date of issue: 05/07/2019

Revision date: 05/07/2019 Supersedes: 09/01/2019

Version: 9.00

## **16. OTHER INFORMATION**

Indication of changes

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

Abbreviations and acronyms:

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

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

Department issuing data specification

sheet: R&D department R&D department Contact person:



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

Page 13

Trade name: ELISA Kits	
CAL B (Cut-Off control),	CAL C (Positive control),
CAL A – E (Standards)	ENZ CONJ Conjugate

Revision date: 05/07/2019 Supersedes: 09/01/2019

Date of issue: 05/07/2019

Version: 9.00

## Full text of H- and EUH-statements:

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

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



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

Page 14

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

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

#### 1.1. Product Identifier

Trade name: STOP SOLN

Products: See first page

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

## 1.2.1. Relevant identified uses

Use of substance/mixture: in vitro diagnostics

## 1.2.2. Uses advised against

No additional information available

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

## Supplier

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

## 1.4. Emergency telephone number

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

## 2. HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture

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

Not classified

### Adverse physicochemical, human health and environmental effect

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

#### 2.2. Label elements

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

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

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

## 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
sulphuric acid	(CAS-No.) 7664-93-9 (EC-No.) 231-639-5 (EC Index-No.) 016-020-00-8 (REACH-no.) 01-2119458838-20-xxxx	< 3	Skin. Corr. 1A, H314

## **Specific concentration limits:**



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

Page 15

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

Name	Product identifier	Specific concentration limits
sulphuric acid	(CAS-No.) 7664-93-9	(5= <c 2,="" <15)="" eye="" h319<="" irrit.="" td=""></c>
	(EC-No.) 231-639-5	(5= <c 2,="" <15)="" h315<="" irrit.="" skin="" td=""></c>
	(EC Index-No.) 016-020-00-8	(C>= 15) Skin Corr. 1A, H314
	(REACH-no.) 01-2119458838-20-xxxx	

Full text of H-statements: see section 16

### 4. FIRST AID MEASURES

## 4.1. Description of the first aid measures

First-aid measures general: In all cases of doubt, or when symptoms persist, seek medical

attention.

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for

breathing.

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

water. Cover wounds with sterile bandage. Get medical advice

if skin irritation persists.

First-aid measures after eye contact: Remove contact lenses, if present and easy to do. Continue

rinsing. In case of contact with eyes, rinse immediately with

plenty of water and seek medical advice.

First-aid measures after ingestion: Rinse mouth out with water. Drink plenty of water. Do NOT

induce vomiting. Call a doctor.

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

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

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

Treat symptomatically.

### 5. FIREFIGHTING MEASURES

## 5.1. Extinguishing media

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

surrounding fire.

Unsuitable extinguishing media: No information available.

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

Hazardous decomposition products

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

5.3. Advice for firefighters

Protection during firefighting: Do not attempt to take action without suitable protective

equipment. Self-contained breathing apparatus. Complete

protective clothing.

Other information: Do not allow run-off from the fire-fighting to enter drains or

water courses. Disposal must be done according to official

regulations.



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

Page 16

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

## 6. ACCIDENTAL RELEASE MEASURES

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

## 6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see sec-

tion 8.

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

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equip-

ment. For further information refer to section 8: "Exposure

controls/personal protection".

### 6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw

dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable con-

tainer for disposal.

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

#### 6.4. Reference to other sections

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

### 7. HANDLING AND STORAGE

## 7.1. Precautions for safe handling

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

skin and eyes. Wear personal protective equipment.

Hygiene measures: Do not eat, drink or smoke when using this product. Always

wash hands after handling the product.

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

Storage conditions: Store in dry, cool, well-ventilated area.

Information about storage in one

common storage facility: Keep away from food, drink and animal feeding stuffs.

## 7.3. Specific end use(s)

In vitro diagnostics.



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

Page 17

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## 8.1. Control parameters

sulphuric acid (7664-93-9)			
EU	Local name	Sulphuric acid (mist)	
EU	IOELV TWA (mg/m <sup>3</sup> )	0.05 mg/m <sup>3</sup>	
EU	Regulatory reference	COMMISSION DIRECTIVE 2009/161/EU	
United Kingdom	Local name	Sulphuric acid	
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	0.05 mg/m³ mist	
United Kingdom	Remark (WEL)	The mist is defined as the thoracic fraction	
United Kingdom	Regulatory reference	EH40. HSE	

## 8.2. Exposure controls

## **Appropriate engineering controls:**

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

## Materials for protective clothing:

Use protective clothing

## Hand protection:

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

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

## Eye protection:

Chemical goggles. EN 166

## Skin and body protection:

Wear suitable protective clothing

## Respiratory protection:

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

### **Environmental exposure controls:**

Avoid release to the environment.

## de medi iec

## SAFETY DATA SHEET

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

Page 18

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

### 9. PHYSICAL AND CHEMICAL PROPERTIES

## 9.1.Information on basic physical and chemical properties

Physical state: liquid
Colour: colourless
Odour: odourless

Odour threshold: no data available.

pH: 1

Relative evaporation rate (butylacetate = 1) no data available Melting point: not applicable Freezing point: no data available Boiling point: no data available Flash point: no data available Auto-ignition temperature: no data available Decomposition temperature: no data available Flammability (solid, gas): not applicable Vapour pressure: no data available Relative vapour density at 20°C: no data available Relative density: no data available Solubility: water: miscible Log Pow: no data available Viscosity, kinematic: no data available Viscosity, dynamic: no data available Explosive properties: product is not explosive Oxidising properties: no data available **Explosive limits:** no data available

9.2. Other information

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

## 10. STABILITY AND REACTIVITY

### 10.1. Reactivity

No additional information available.

## 10.2. Chemical stability

No decomposition if stored normally.

## 10.3. Possibility of hazardous reactions

Reacts violently with: metals

## 10.4. Conditions to avoid

heat

## 10.5. Incompatible materials

metals.

## 10.6 Hazardous decomposition products

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



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

Page 19

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

### 11. TOXICOLOGICAL INFORMATION

## 11.1. Information on toxicological effects

Acute toxicity (oral): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (dermal): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (inhalation): not classified (Based on available data, the classification crite-

ria are not met)

Skin corrosion/irritation: not classified (Based on available data, the classification crite-

ria are not met)

ph: 1

Additional information: Repeated or prolonged skin contact may cause irritation

Serious eye damage/irritation: not classified (Based on available data, the classification crite-

ria are not met)

ph: 1

Additional information: Slight eye irritant upon direct contact

Respiratory or skin sensitisation: not classified (Based on available data, the classification crite-

ria are not met)

Germ cell mutagenicity: not classified (Based on available data, the classification crite-

ria are not met)

Carcinogenicity: not classified (Based on available data, the classification crite-

ria are not met)

Reproductive toxicity: not classified (Based on available data, the classification crite-

ria are not met)

STOT-single exposure: not classified (Based on available data, the classification crite-

ria are not met)

STOT-repeated exposure: not classified (Based on available data, the classification crite-

ria are not met)

sulphuric acid (7664-93-9)

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

Aspiration hazard: not classified (Based on available data, the classification crite-

ria are not met)

## de medi iec

## **SAFETY DATA SHEET**

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

Page 20

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

### 12. ECOLOGICAL INFORMATION

## 12.1. Toxicity

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

aquatic organisms

Acute aquatic toxicity: not classified (Based on available data, the classification crite-

ria are not met)

Chronic aquatic toxicity: not classified (Based on available data, the classification crite-

ria are not met)

12.2. Persistence and degradability

oo ama aogradaaamiy	
Stopping Solution	
Persistence and degradability	No additional information available

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

12.3. Bioaccumulative potential

Stopping Solution	
Bioaccumulative potential	No additional information available

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

### 12.4. Mobility in soil

Stopping Solution	
Ecology - soil	No additional information available

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

## 12.5. Results of PBT and vPvB assessment

## **Stopping Solution**

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## 12.6. Other adverse effects

Other adverse effects: No additional information available.

## 13. DISPOSAL CONSIDERATIONS

## 13.1. Waste treatment methods

Waste treatment methods: Disposal must be done according to official regulations. Euro-

pean waste catalogue. Do not dispose of with domestic waste.

Do not discharge into drains or the environment.

Product/Packaging disposal

recommendations: Dirty containers cannot be handled as normal waste. Disposal

must be done according to official regulations.

European List of Waste (LoW) code: 16 05 06\* - laboratory chemicals consisting of or containing

dangerous substances including mixtures of laboratory chemi-

cals

15 01 02 - plastic packaging

# de medi

## SAFETY DATA SHEET

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

Page 21

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

## 14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN number	Not	Not	Not	Not	Not
14.1. ON Humber	applicable	applicable	applicable	applicable	applicable
14.2. UN proper shipping name	Not	Not	Not	Not	Not
14.2. ON proper shipping name	applicable	applicable	applicable	applicable	applicable
14.3. Transport hazard class(es)	Not	Not	Not	Not	Not
14.5. Transport flazard class(es)	applicable	applicable	applicable	applicable	applicable
14.4 Packing group	Not	Not	Not	Not	Not
14.4 Packing group	applicable	applicable	applicable	applicable	applicable
14.5. Environmental hazards	Not	Not	Not	Not	Not
14.5. Environmental hazards	applicable	applicable	applicable	applicable	applicable
No:	No supplementary information available				

## 14.6. Special precautions for user

- Overland transport: Not applicable
- Transport by sea: Not applicable
- Air transport: Not applicable
- Inland waterway transport: Not applicable
- Rail transport: Not applicable

## 14.7. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable

## 15. REGULATORY INFORMATION

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regula 1907/2006:	ation (EC) No.
3 Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No. 1272/2008	sulphuric acid
3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No. 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	sulphuric acid

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances

## 15.1.2. National regulations

No additional information available

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

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



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

Page 22

Trade name: ELISA Kits (see first page)

STOP SOLN

Date of issue: 09/18/2017 Revision date: 09/18/2017 Supersedes: 09/19/2016 Version: 7.00

## **16. OTHER INFORMATION**

Indication of changes

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

Abbreviations and acronyms:

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

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

Department issuing data specification

sheet: R&D department Contact person: R&D department

Full text of H- and EUH-statements:

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

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

## de medi iec

## SAFETY DATA SHEET

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

Page 23

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

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

## 1.1. Product Identifier

Trade name:

SUB TMB

Products: See first page

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

## 1.2.1. Relevant identified uses

Use of substance/mixture: Substrate solution for immunoassays

#### 1.2.2. Uses advised against

No additional information available

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

## Supplier

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

#### 1.4. Emergency telephone number

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

## 2. HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

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

Not classified

## Adverse physicochemical, human health and environmental effect

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

#### 2.2. Label elements

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

No labelling applicable.

### 2.3. Other hazards

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

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

## 3.1. Substances

Not applicable

## 3.2. Mixtures

Comments: Nonhazardous mixture

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

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

Page 24

Trade name: ELISA Kits (see first page)

Date of issue: 16/04/2020 SUB TMB Revision date: 16/04/2020

Version: 1.00

#### 4. FIRST AID MEASURES

## 4.1. Description of the first aid measures

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

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for

breathing. If symptoms persist, call a physician.

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

water.

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

eyelids.

Rinse mouth out with water. Drink plenty of water. Call a doc-First-aid measures after ingestion:

tor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

#### FIREFIGHTING MEASURES

## 5.1. Extinguishing media

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

Unsuitable extinguishing media: No information available.

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

Hazardous decomposition products in case of fire:

Toxic fumes may released. Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Protection during firefighting: Do not attempt to take action without suitable protective

equipment. Self-contained breathing apparatus. Complete

protective clothing.

Do not allow run-off from the fire-fighting to enter drains or Other information:

water courses. Disposal must be done according to official

regulations.

## **ACCIDENTAL RELEASE MEASURES**

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

## 6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see sec-

tion 8.

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

qualified personnel equipped with suitable protective equip-

ment may intervene.

#### 6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equip-

ment. For further information refer to section 8: "Exposure

controls/personal protection".

## 6.2. Environmental precautions

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



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

Page 25

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

6.3. Methods and material for containment and cleaning up

Take up liquid spill into absorbent material, e.g.: sand, saw Methods for cleaning up:

dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Notify authorities if product enters sewers

or public waters.

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

### 6.4. Reference to other sections

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

### 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Ensure good ventilation of the work station. Wear personal Precautions for safe handling:

protective equipment.

Separate working clothes from town clothes. Launder sepa-Hygiene measures:

rately. Do not eat, drink or smoke when using this product. Al-

ways wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a dry place. Store in a closed container. Containers

> which are opened should be properly resealed and kept upright to prevent leakage. Store in a well-ventilated place. Keep

cool.

Storage temperature: 2-8°C

Information about storage in one

common storage facility:

Keep away from food, drink and animal feeding stuffs. Storage area:

Protect from light: Protect from moisture. Store away from

heat.

### 7.3. Specific end use(s)

Follow the directions.



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

Page 26

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

## Appropriate engineering controls:

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

## Hand protection:

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

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

## Eye protection:

Safety goggles, EN 166

## Skin and body protection:

Wear suitable protective clothing. EN 14605

## **Respiratory protection:**

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

## **Environmental exposure controls:**

Avoid release to the environment.

#### Other information:

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



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

Page 27

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

### 9. PHYSICAL AND CHEMICAL PROPERTIES

## 9.1. Information on basic physical and chemical properties

Physical state: liquid
Colour: colourless
Odour: characteristic
Odour threshold: no data available.

pH: 3.5-4

Relative evaporation rate (butylacetate = 1) no data available Melting point: not applicable reezing point: no data available

Boiling point: 101 °C

Flash point: no data available Auto-ignition temperature: no data available Decomposition temperature: no data available Flammability (solid, gas): not applicable Vapour pressure: no data available Relative vapour density at 20°C: no data available Relative density: no data available Density 1.011 g/cm<sup>3</sup>

Solubility:
Log Pow:
Viscosity, kinematic:
Viscosity, dynamic:
Explosive properties:

Water: solubleMiscible
no data available
product is not explosive

Oxidising properties:

non oxidizing
Explosive limits:

no data available

9.2. Other information

Other properties: No additional information available.

## 10. STABILITY AND REACTIVITY

### 10.1. Reactivity

No additional information available.

## 10.2. Chemical stability

No decomposition if stored normally.

## 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

## 10.4. Conditions to avoid

Water, humidity. All heat sources, including direct sunlight

### 10.5. Incompatible materials

Strong oxidizing agent. Metals. Metallic salts.

## 10.6 Hazardous decomposition products

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



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

Page 28

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

#### 11. TOXICOLOGICAL INFORMATION

## 11.1. Information on toxicological effects

Acute toxicity (oral): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (dermal): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (inhalation): not classified (Based on available data, the classification crite-

ria are not met)

Skin corrosion/irritation: not classified (Based on available data, the classification crite-

ria are not met)

pH: 3.5-4

Additional information: Repeated or prolonged skin contact may cause irritation

Serious eye damage/irritation: not classified (Based on available data, the classification crite-

ria are not met)

pH: 3.5-4

Respiratory or skin sensitisation: not classified (Based on available data, the classification crite-

ria are not met)

Germ cell mutagenicity: not classified (Based on available data, the classification crite-

ria are not met)

Carcinogenicity: not classified (Based on available data, the classification crite-

ria are not met)

Reproductive toxicity: May damage the unborn child.

STOT-single exposure: not classified (Based on available data, the classification crite-

ria are not met)

STOT-repeated exposure: not classified (Based on available data, the classification crite-

ria are not met)

Aspiration hazard: not classified (Based on available data, the classification crite-

ria are not met)

## 12. ECOLOGICAL INFORMATION

### 12.1. Toxicity

Hazardous to the aquatic environment, short term (acute):

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

Hazardous to the aquatic environment, long term (chronic):

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

12.2. Persistence and degradability

SUB TMB	
Persistence and degradability	No additional information available

## 12.3. Bioaccumulative potential

SUB TMB	
Bioaccumulative potential	No additional information available

## 12.4. Mobility in soil

SUB TMB	
Ecology - soil	No additional information available



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

Page 29

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

## 12.5. Results of PBT and vPvB assessment

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

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

#### 12.6. Other adverse effects

Other adverse effects: No additional information available.

## 13. DISPOSAL CONSIDERATIONS

## 13.1. Waste treatment methods

Waste treatment methods:

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

Product/Packaging disposal

recommendations:

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

pose of in compliance with current legislation.

## 14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN number	Not	Not	Not	Not	Not
14.1. ON Humber	applicable	applicable	applicable	applicable	applicable
14.2. UN proper shipping	Not	Not	Not	Not	Not
name	applicable	applicable	applicable	applicable	applicable
14.3. Transport hazard	Not	Not	Not	Not	Not
class(es)	applicable	applicable	applicable	applicable	applicable
14.4 Packing group	Not	Not	Not	Not	Not
14.4 Facking group	applicable	applicable	applicable	applicable	applicable
14.5. Environmental hazards	Not	Not	Not	Not	Not
14.5. Environmental nazarus	applicable	applicable	applicable	applicable	applicable
No supplementary information available					

## 14.6. Special precautions for user

Overland transport: Not applicable

Transport by sea: Not applicable

Air transport: Not applicable

Inland waterway transport: Not applicable

Rail transport: Not applicable

## 14.7. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable



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

Page 30

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

### 15. REGULATORY INFORMATION

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

## 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions.

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances

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

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

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

## 15.1.2. National regulations

United Kingdom

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

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

## de medi iec

## **SAFETY DATA SHEET**

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

Page 31

Trade name: ELISA Kits (see first page)

SUB TMB

Date of issue: 16/04/2020 Revision date: 16/04/2020

Version: 1.00

## **16. OTHER INFORMATION**

Abbreviations and acronyms:

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

Data sources:

MSDS of the supplier.

Department issuing data specification sheet:

R&D department

Contact person:

R&D department

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

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

Page 32

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/ 2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

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

#### 1.1. **Product identifier**

WASH SOLN Trade name:

Products: See first page

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

#### 1.2.1 Relevant identified uses

Use of the substance/ mixture: In vitro diagnostics

### 1.2.2. Uses advised against

No additional information available

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

## Supplier

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

### 1.4. Emergency telephone number

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

## 2. HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

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

#### 2.2. Label elements

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

#### 2.3. Other hazards

This substance/ mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/ mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 3. **COMPOSITION/ INFORMATION ON INGREDIENTS**

#### 3.1. Substances

Not applicable

#### 3.2. **Mixtures**

Comments: Aqueous solution of special active agents

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

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

Page 33

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/ 2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

## **SECTION 4: FIRST AID MEASURES**

#### Description of first aid measures 4.1.

First-aid measures general: In all cases of doubt, or when symptoms persist, seek medical

attention

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breath-

ing.

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

ter. Cover wounds with sterile bandage. Get medical advice if

skin irritation persists.

Remove contact lenses, if present and easy to do. Continue First-aid measures after eye contact:

rinsing. In case of contact with eyes, rinse immediately with

plenty of water and seek medical advice.

Rinse mouth out with water. Drink plenty of water. Do NOT First-aid measures after ingestion:

induce vomiting. Call a doctor.

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

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

## Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## 5. SECTION 5: FIREFIGHTING MEASURES

### Extinguishing media

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

surrounding fire.

No information available. Unsuitable extinguishing media:

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

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

case of fire:

Advice for firefighters

Protection during firefighting: Do not attempt to take action without suitable protective equip-

ment. Self-contained breathing apparatus. Complete protec-

tive clothing.

Other information: Do not allow run-off from fire fighting to enter drains or water

courses. Disposal must be done according to official regula-

tions.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

## Personal precautions, protective equipment and emergency procedures

## 6.1.1. For non-emergency personnel

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

Emergency procedures: Ventilate spillage area.

## 6.1.2. For emergency responders

Do not attempt to take action without suitable protective equip-Protective equipment:

ment. For further information refer to section 8: "Exposure

controls/ personal protection".

#### 6.2. **Environmental precautions**

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



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

Page 34

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/ 2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

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

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw

dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shoveling) and collect in suitable con-

tainer for disposal.

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

#### 6.4. Reference to other sections

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

## 7. SECTION 7: HANDLING AND STORAGE

## 7.1. Precautions for safe handling

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

skin and eyes.

Wear Personal protective equipment.

Hygiene measures: Do not eat, drink or smoke when using this product. Always

wash hands after handling the product.

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

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

Information about storage in one

Common storage facility

Keep away from food, drink and animal feeding stuffs.

## 7.3. Specific end use(s)

In vitro diagnostics.

## 8. SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

## 8.1. Control parameters

No additional information available.

### 8.2. Exposure controls

Appropriate engineering controls:

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

#### Hand protection:

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

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

Eye protection: Chemical goggles. EN 166

Skin and body protection: Wear suitable protective clothing

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

Environmental exposure controls: Avoid release to the environment.

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

Page 35

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/ 2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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

Physical sate: Liquid Colour: colourless Odour: odourless

Odour threshold: No data available pH: 7 - 7.4 (20 C)Relative evaporation rate (butylacetate=1): No data available Melting point: Not applicable Freezing point: No data available Boiling point: No data available Flash point: No data available Auto-ignition temperature: No data available Decomposition temperature: No data available Flammability (solid, gas): Not applicable Vapour pressure: No data available Relative vapour density at 20 C: No data available Relative density: No data available Water: Miscible Solubility: No data available Log Pow: Viscosity, kinematic: No data available Viscosity, dynamic: No data available Explosive properties: Product is not explosive. Oxidising properties: No data available No data available

**Explosive limits:** 

Other information 9.2.

VOC content: 0 %

### 10. SECTION 10: STABILITY AND REACTIVITY

#### 10.1. Reactivity

No additional information available.

## Chemical stability

No decomposition if stored normally.

## Possibility of hazardous reactions:

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

Heat.

#### 10.5. Incompatible materials

No additional information available

## Hazardous decomposition products

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



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

Page 36

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

## 11. SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (oral): Not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (dermal): Not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (inhalation): Not classified (Based on available data, the classification crite-

ria are not met)

Skin corrosion/ irritation: Not classified (Based on available data, the classification crite-

ria are not met) pH: 7 – 7.4 (20 C)

Additional information: Repeated or prolonged skin contact may cause irritation

Serious eye damage/ irritation: Not classified (Based on available data, the classification crite-

ria are not met) pH: 7 – 7.4 (20 C)

Additional information: Slight eye irritant upon direct contact.

Respiratory or skin sensitization: Not classified (Based on available data, the classification crite-

ria are not met)

Germ cell mutagenicity: Not classified (Based on available data, the classification crite-

ria are not met)

Carcinogenicity: Not classified (Based on available data, the classification crite-

ria are not met)

Reproductive toxicity: Not classified (Based on available data, the classification crite-

ria are not met)

STOT-single exposure: Not classified (Based on available data, the classification crite-

ria are not met)

STOT-repeated exposure: Not classified (Based on available data, the classification crite-

ria are not met)

Aspiration hazard: Not classified (Based on available data, the classification crite-

ria are not met)



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

Page 37

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/ 2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

#### 12. SECTION 12: ECOLOGICAL INFORMATION

**12.1. Toxicity** Ecology – general:

Before neutralization, the product may represent a danger to

aquatic organisms.

Acute aquatic toxicity: Not classified (Based on available data, the classification crite-

ria are not met)

Chronic aquatic toxicity: Not classified (Based on available data, the classification crite-

ria are not met)

12.2. Persistence and degradability

· - · - · · · · · · · · · · · · · · · ·	
WASH SOLN	
Persistence and degradability	No additional information available.

12.3. Bioaccumulative potential

WASH SOLN	
Bioaccumulative potential	No additional information available.

12.4. Mobility in soil

WASH SOLN	
Ecology - soil	No additional information available.

#### 12.5. Results of PBT and vPvB assessment

WASH	SOLN
------	------

This substance/ mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/ mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Other adverse effects

Other adverse effects: No additional information available.

#### 13. SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1. Waste treatment methods

Waste treatment methods: Disposal must be done according to official regulations. Euro

pean waste Catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

Product/ Packaging disposal

recommendations: Dirty containers cannot be handled as normal waste. Disposal

must be done according to official regulations.

European List of Waste (LoW) code: 16 05 06\* - laboratory chemicals consisting of or containing

dangerous substances including mixtures of laboratory chemi-

cals

15 01 02 - plastic packaging



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

Page 38

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/ 2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

#### 14. SECTION 14: TRANSPORT INFORMATION

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

ADR	IMDG	IATA	AND	RID	
14.1. UN number					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.2. UN proper	shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.3. Transport	14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.4. Packing gr	14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.5. Environmental hazards					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
No supplementary information available					

# 14.6. Special precautions for user

- Overland transport: Not applicable
- Transport by sea: Not applicable
- Air transport: Not applicable
- Inland waterway transport: Not applicable
- Rail transport: Not applicable

# 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

# 15. SECTION 15: REGULATORY INFORMATION

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

# 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

VOC content: 0 %

Other information, restriction and prohibition A safety data sheet is not required for this product un-

der Article 31 of REACH.

regulations: This product Safety Information Sheet has been created

on a voluntary basis.

#### 15.1.2. National regulations

No additional information available

# 15.2. Chemical safety assessment

No chemical safety assessment has been carried out



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

Page 39

Trade name: ELISA Kits (see first page)

WASH SOLN

Date of issue: 09/22/ 2017 Revision date: 09/22/2017 Supersedes: 09/19/2016

Version: 7.00

#### 16. SECTION 16: OTHER INFORMATION

Indication of changes:

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

Abbreviations and acronyms:

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

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

Department issuing data specification

sheet: R&D department Contact person: R&D department

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

# de medi iec

# **SAFETY DATA SHEET**

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

Page 40

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

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

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

#### 1.1. Product Identifier

Trade name: SAM DIL, CAL A (Negative Control)

Products: See first page

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

#### 1.2.1. Relevant identified uses

Use of substance/mixture: in vitro diagnostics

### 1.2.2. Uses advised against

No additional information available

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

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

#### 1.4. Emergency telephone number

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

#### 2. HAZARDS IDENTIFICATION

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

Skin sensitisation, Category 1 H317

Full text of H statements: see section 16

# Adverse physicochemical, human health and environmental effect

May cause an allergic skin reaction.

#### 2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) Warning

Hazardous ingredients reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no.0247-

500-7), and 2-methyl-2H-isothiazol-3-one (EC no. 220-239-6) (3:1)

Hazard statements (CLP) H317: May cause an allergic skin reaction. Precautionary statements (CLP)P261: Avoid breathing mist, vapours, spray.

P280: Wear protective gloves.

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

P333+P313: If skin irritation or rash occurs: Get medical advice/atten-

tion.

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

EUH-statements EUH032 – Contact with acids liberates very toxic gas.

MSDS RUO Veterinary products 211013 e.docx



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

Page 41

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

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

Version: 9.00

#### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Comments: Solvent mixture with additives

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
sodium azide substance with a Community workplace exposure limit substance with national workplace exposure limit(s) (GB)	(CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index-No.) 011-004-00-7	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation:dust,mist), H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)	(CAS-No.) 55965-84-9 (EC Index-No.) 613-167-00-5			
Specific concentration limits:				
Name	Product identifier	Specific concentration limits		
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3- one [EC no. 247-500-7], and 2-methyl-2H -isothiazol- 3-one [EC no. 220-239-6] (3:1)	(CAS-No.) 55965-84-9 (EC Index-No.) 613-167-00-5	(0.06 = <c (0.06 =<c< td=""><td colspan="2">( 0.0015 =<c 1,="" 100)="" <="" h317<br="" sens.="" skin="">( 0.06 =<c 0.6)="" 2,="" <="" eye="" h319<br="" irrit.="">( 0.06 =<c 0.6)="" 2,="" <="" h315<br="" irrit.="" skin="">( 0.6 =<c 100)="" 1b,="" <="" corr.="" h314<="" skin="" td=""></c></c></c></c></td></c<></c 	( 0.0015 = <c 1,="" 100)="" <="" h317<br="" sens.="" skin="">( 0.06 =<c 0.6)="" 2,="" <="" eye="" h319<br="" irrit.="">( 0.06 =<c 0.6)="" 2,="" <="" h315<br="" irrit.="" skin="">( 0.6 =<c 100)="" 1b,="" <="" corr.="" h314<="" skin="" td=""></c></c></c></c>	

# **Specific concentration limits:**

Name	Product identifier	Specific concentration limits
	(CAS-No.) 55965-84-9 (EC Index-No.) 613-167-00-5	( 0.0015 = <c 1,="" 100)="" <="" h317<br="" sens.="" skin="">( 0.06 =<c 0.6)="" 2,="" <="" eye="" h319<br="" irrit.="">( 0.06 =<c 0.6)="" 2,="" <="" h315<br="" irrit.="" skin="">( 0.6 =<c 100)="" 1b,="" <="" corr.="" h314<="" skin="" td=""></c></c></c></c>

Full text of H-statements: see section 16



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

Page 42

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

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

Version: 9.00

#### 4. FIRST AID MEASURES

#### 4.1. Description of the first aid measures

First-aid measures general: In all cases of doubt, or when symptoms persist, seek medical

attention.

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for

breathing.

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

ter. Cover wounds with sterile bandage. Get medical advice if skin irritation persists. Wash skin with plenty of water. If skin

irritation or rash occurs: get medical advice/attention.

First-aid measures after eye contact: Remove contact lenses, if present and easy to do. Continue

rinsing. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Rinse eyes with wa-

ter as a precaution.

First-aid measures after ingestion: Rinse mouth out with water. Drink plenty of water. Do NOT

induce vomiting. Call a doctor. Call a poison center or a doctor

if you feel unwell.

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

Symptoms/effects: No additional information available.

Symptoms/effects after skin contact: May cause slight irritation. May cause an allergic skin reac-

tion.

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

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

Treat symptomatically.

# 5. FIREFIGHTING MEASURES

### 5.1. Extinguishing media

Suitable extinguishing media: Water spray. Dry powder. Foam. Carbon dioxide. Use extin-

guishing media appropriate for surrounding fire.

Unsuitable extinguishing media: Strong water jet

# 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products

in case of fire: Toxic fumes may be released. Nitrogen oxides. Carbon mon-

oxide. Carbon dioxide.

5.3. Advice for firefighters

Protection during firefighting: Do not attempt to take action without suitable protective

equipment. Self-contained breathing apparatus. Complete

protective clothing.

Other information: Do not allow run-off from the fire-fighting to enter drains or

water courses. Disposal must be done according to official

regulations.



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

Page 43

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

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

Version: 9.00

#### 6. ACCIDENTAL RELEASE MEASURES

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

6.1.1. For non-emergency personnel

Protective equipment: Concerning personal protective equipment to use, see sec-

tion 8.

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

Avoid breathing mist, vapours, spray.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equip-

ment. For further information refer to section 8: "Exposure

controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material, e.g.: sand, saw

dust. Wash away remainder with plenty of water. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Wash away remainder with plenty of water.

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

6.4. Reference to other sections

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

#### 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Wear personal

protective equipment. Avoid contact with skin and eyes. Avoid

breathing mist, vapours, spray.

Hygiene measures: Do not eat, drink or smoke when using this product. Always

wash hands after handling the product. Contaminated work clothing should be allowed out of the workplace. Wash con-

taminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

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

Information about storage in one

common storage facility: Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

In vitro diagnostics.



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

Page 44

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

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

Version: 9.00

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters

sodium azide (26628-22-8)				
EU	Local name	Sodium azide		
EU	IOELV TWA (mg/m³)	0.1 mg/m³		
EU	IOELV STEL (mg/m³)	0.3 mg/m³		
EU	Notes	Skin		
EU	D Regulatory reference COMMISSION DIRECTIVE 2000/39/EC			
sodium azide (26628-22-8)				
United Kingdom	Local name	Sodium azide		
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³ (as NaN3)		
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m³ (as NaN3)		
United Kingdom	Remark (WEL)	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)		
United Kingdom	Regulatory reference	EH40/2005 (Third edition, 2018). HSE		

#### 8.2. Exposure controls

# Appropriate engineering controls:

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

#### Hand protection:

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

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

#### Eye protection:

Chemical goggles. EN 166

# Skin and body protection:

Wear suitable protective clothing. EN 340. EN 13034

# **Respiratory protection:**

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

#### **Environmental exposure controls:**

Avoid release to the environment.

#### Other information

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



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

Page 45

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

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

Version: 9.00

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1.Information on basic physical and chemical properties

Physical state: liquid
Colour: various
Odour: odourless

Odour threshold: no data available.  $7 - 8.2 (20^{\circ}C)$ pH: Relative evaporation rate (butylacetate = 1) no data available Melting point: not applicable Freezing point: no data available Boiling point: no data available Flash point: no data available Auto-ignition temperature: no data available Decomposition temperature: no data available Flammability (solid, gas): not applicable Vapour pressure: no data available Relative vapour density at 20°C: no data available Relative density: no data available Solubility: water: miscible Log Pow: no data available Viscosity, kinematic: no data available Viscosity, dynamic: no data available

Explosive properties: product is not explosive

Oxidising properties: no data available Explosive limits: no data available

9.2. Other information

VOC content: 0 %



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

Page 46

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

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

Version: 9.00

#### 10. STABILITY AND REACTIVITY

# 10.1. Reactivity

No additional information available.

# 10.2. Chemical stability

No decomposition if stored normally.

#### 10.3. Possibility of hazardous reactions

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

#### 10.4. Conditions to avoid

heat

#### 10.5. Incompatible materials

No additional information available. Acids.

# 10.6 Hazardous decomposition products

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

#### 11. TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

Acute toxicity (oral): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (dermal): not classified (Based on available data, the classification crite-

ria are not met)

Acute toxicity (inhalation): not classified (Based on available data, the classification crite-

ria are not met)

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

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9)	
LD50 oral rat	53 mg/kg
LD50 dermal rat	660 mg/kg
LC50 inhalation rat (Dust/Mist - mg/l/4h)	2.36 mg/l/4h

Skin corrosion/irritation: not classified (Based on available data, the classification crite-

ria are not met) ph: 7 – 8.2 (20°C)

Additional information: Repeated or prolonged skin contact may cause irritation

Serious eye damage/irritation: not classified (Based on available data, the classification crite-

ria are not met) ph: 7 – 8.2 (20°C)

Additional information: Slight eye irritant upon direct contact

Respiratory or skin sensitisation: not classified (Based on available data, the classification crite-

ria are not met)

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

Page 47

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

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

Version: 9.00

Germ cell mutagenicity: not classified (Based on available data, the classification crite-

ria are not met)

Carcinogenicity: not classified (Based on available data, the classification crite-

ria are not met)

Reproductive toxicity: not classified (Based on available data, the classification crite-

ria are not met)

STOT-single exposure: not classified (Based on available data, the classification crite-

ria are not met)

STOT-repeated exposure: not classified (Based on available data, the classification crite-

ria are not met)

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

Aspiration hazard: not classified (Based on available data, the classification crite-

ria are not met)

#### 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology – general: May cause pH changes in aqueous ecological systems. Acute aquatic toxicity:

not classified (Based on available data, the classification crite-

ria are not met)

Chronic aquatic toxicity: not classified (Based on available data, the classification crite-

ria are not met)

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

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9)	
LC50 fish 1	0.22 mg/l (96h, Oncorhynchus mykiss, (OECD 201 method))
EC50 Daphnia 1	0.1 mg/l (48h, Daphnia magna, (OECD 202 method))
ErC50 (algae) 0.048 mg/l (72h, Pseudokirchneriella subcapitata, (OECD 201 method))	
NOEC chronic fish 0.098 mg/l (28 d, Oncorhynchus mykiss, (OECD 210 method))	
IOEC chronic crustacea 0.004 mg/l (21 d, Daphnia magna, (OECD 211 method))	

# 12.2. Persistence and degradability

SAM DIL, CAL A (Negative control)	
Persistence and degradability	No additional information available

Sodium azide (26628-22-8)	
Persistence and degradability	Not relevant

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no.0247-500-7), and 2-methyl-2H-isothiazol-3-one (EC no. 220-239-6) (3:1) (55965-84-9)	
Persistence and degradability	Readily biodegradable
Biodegradation	>60 % (OECD 301B method)



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

Page 48

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

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

Version: 9.00

12.3. Bioaccumulative potential

SAM DIL, CAL A (Negative control)	
Bioaccumulative potential	No additional information available

Sodium azide (26628-22-8)	dium azide (26628-22-8)	
Log Pow	Not applicable	

12.4. Mobility in soil

SAM DIL, CAL A (Negative control)	
Ecology - soil	No additional information available

Sodium azide (26628-22-8)	
Log Koc	= 2.62. (20°C; (OECD 106 method))

#### 12.5. Results of PBT and vPvB assessment

SAM DIL, CAL A (Negative control)
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Other adverse effects

Other adverse effects: No additional information available.

#### 13. DISPOSAL CONSIDERATIONS

# 13.1. Waste treatment methods

Waste treatment methods: Disposal must be done according to official regulations. Euro-

pean waste catalogue. Do not dispose of with domestic waste.

Do not discharge into drains or the environment.

Product/Packaging disposal

recommendations:

Dirty containers cannot be handled as normal waste. Disposal

must be done according to official regulations.

European List of Waste (LoW) code: 16 05 06\* - laboratory chemicals consisting of or containing

dangerous substances including mixtures of laboratory chemi-

cals

15 01 02 - plastic packaging

HP12 - Release of an acute toxic gas; waste which releases

acute toxic gases (Acute Tox. 1,2 or 3) in contact with water or

an acid

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

respiratory organs.



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

Page 49

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

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

Version: 9.00

#### 14. TRANSPORT INFORMATION

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

	ADR	IMDG	IATA	ADN	RID
14.1. UN number	Not	Not	Not	Not	Not
14.1. ON Humber	applicable	applicable	applicable	applicable	applicable
14.2. UN proper shipping name	Not	Not	Not	Not	Not
14.2. ON proper shipping hame	applicable	applicable	applicable	applicable	applicable
14.3. Transport hazard class(es)	Not	Not	Not	Not	Not
14.5. Transport flazaru class(es)	applicable	applicable	applicable	applicable	applicable
14.4 Packing group	Not	Not	Not	Not	Not
14.4 Facking group	applicable	applicable	applicable	applicable	applicable
14.5. Environmental hazards	Not	Not	Not	Not	Not
14.5. Environmental hazarus	applicable	applicable	applicable	applicable	applicable
No supplementary information available					

### 14.6. Special precautions for user

- Overland transport
   Not applicable
- Transport by sea Not applicable
- Air transport Not applicable
- Inland waterway transport Not applicable
- Rail transport Not applicable

# 14.7. Transport in bulk according to Annex II of Marpol and the IBC code

Not applicable

#### 15. REGULATORY INFORMATION

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

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances

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

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

VOC content: 0 9

Other information, restriction and prohibition regulation:

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

### 15.1.2. National regulations

No additional information available



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

Page 50

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

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

Version: 9.00

# 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

# **16. OTHER INFORMATION**

Indication of changes

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

Abbreviations and acronyms:

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

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

Department issuing data specification

sheet: R&D department Contact person: R&D department



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

Page 51

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

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

Version: 9.00

#### Full text of H- and EUH-statements:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

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

Skin Sens. 1 H317 Calculation method

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