

## Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 10.11.2020

Version: 004

replaced Version: 28.05.2020

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### **ELISA Autoimmunity**

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#### Product identifier

Product name:

**ELISA Autoimmunity**

Product number:

**10xxx\***

<b>Article Name</b>	<b>Symbol</b>	<b>MSDS Version</b>	<b>Appendix</b>
<b>Break apart microtiter test strips</b>	<b>MP</b>	011	(1)
<b>Calibrator A – F</b>	<b>CAL</b>	011	(2)
<b>Cut-off Calibrator</b>	<b>CO-CAL</b>	011	(2)
<b>Positive Control</b>	<b>CON +</b>	011	(2)
<b>Negative Control</b>	<b>CON –</b>	011	(2)
<b>Sample Buffer, 5x conc.</b>	<b>SB 5x</b>	011	(3)
<b>Wash Buffer, 50x conc.</b>	<b>WASHB 50x</b>	011	(4)
<b>Anti-Human IgA, IgG or IgM Conjugate</b>	<b>CONJ</b>	011	(5)
<b>Substrate</b>	<b>SUB</b>	012	(6)
<b>Stop Solution</b>	<b>STOP</b>	011	(7)
<b>Recovery**</b>	<b>RC</b>	011	(8)

\* except Ref 10602-10606, 10810, 10901-10903

\*\* only in Ref 10402

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Always read the intended use before using the test kit. General terms and conditions apply.

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Tabel	New version of all articles
Notes	New inserted

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### Appendix 1 – Safety Data Sheet

**Break apart microtiter test strips**

**MP**

#### Section 1: Identification of the substance/mixture and of the company

##### 1.1 Product identifier

Product name:

Symbol:

**Break apart microtiter test strips**

**MP**

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

Dr.-Karl-Aschoff-Straße 9

55543 Bad Kreuzbach

Germany

Tel. +49 (0) 671 – 920 650 – 90

Fax +49 (0) 671 – 920 650 – 91

E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

##### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

#### Section 2: Hazards identification

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

###### Classification (Regulation (EC) No. 1272/2008)

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** Not applicable.

##### 2.2 Label elements

Pictogram: None

Signal word: None

Hazard statements: None

Precaution phrases: None

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.

##### 2.3 Other hazards

This product is not classified as PBT or vPvB.

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### Section 3: Composition/information on ingredients

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#### 3.1 Substance

Not applicable.

#### 3.2 Mixture

Not applicable.

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### Section 4: First aid measures

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#### 4.1 Description of first aid measures

After inhalation: Not applicable.

After skin contact: Not applicable.

After eye contact: Not applicable.

After swallowing: Not applicable.

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

No information available.

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

Treat symptomatically.

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### Section 5: Firefighting measures

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#### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

None known.

#### 5.2 Special hazards arising from the substance or measure

Not combustible. Ambient fire may liberate hazardous vapours.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters.

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

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### Section 6: Accidental release measures

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

##### 6.1.1 Advice for non-emergency personnel

Do not breathe vapours, aerosols. Evacuate the danger area, observe emergency procedures, consult an expert.

##### 6.1.2 Advice for emergency responders

Personal protection equipment: see section 8

#### 6.2 Environmental precautions

Do not allow to enter into surface water or drains.

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

Take up mechanically, placing in appropriate containers for disposal.

#### 6.4 Reference to other sections

Disposal: see section 13

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### Section 7: Handling and storage

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#### 7.1 Precautions for safe handling

##### 7.1.1 Advice on safe handling

See labelling. When using do not eat and drink. Thorough skin-cleansing after handling the product.

##### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

##### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 13 (non-combustible solids)

#### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

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### Section 8: Exposure controls/personal protection

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#### 8.1 Control parameters

No data available.

#### 8.2 Exposure controls

##### 8.2.1 Engineering measures

Provide adequate ventilation.

##### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work.

Draw up and observe protection program.

##### 8.2.2.1 Eye/Face protection

Not required.

##### 8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile rubber or butyl rubber. The protective gloves to be used must comply with the specifications of Regulation (EU) 2016/425 and the related standard EN374.

##### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

##### 8.2.2.4 Respiratory protection

Not required.

#### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

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### Section 9: Physical and chemical properties

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

Form	solid
Colour	colourless
Odour	odourless
Odour Treshold	Not applicable.
pH	Not applicable.
Melting point	No information available.

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Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available.
Water solubility	Not soluble.
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	None.
<b>9.2 Other data</b>	
No additional information.	

### **Section 10: Stability and reactivity**

- 10.1 Reactivity**  
See section 10.3.
- 10.2 Chemical stability**  
Recommended storage temperature: +2 to +8 °C.
- 10.3 Possibility of hazardous reactions**  
No information available.
- 10.4 Conditions to avoid**  
Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).
- 10.5 Incompatible materials**  
No information available.
- 10.6 Hazardous decomposition products**  
No information available.

### **Section 11: Toxicological information**

- 11.1 Information on toxicological effects**
- Acute oral toxicity**  
Not applicable.
  - Acute inhalation toxicity**  
Not applicable.
  - Acute dermal toxicity**  
Not applicable.
  - Skin corrosion/irritation**  
Not applicable.
  - Serious eye damage/irritation**  
Not applicable.
  - Skin sensitization**  
Not applicable.
  - Germ cell mutagenicity**  
Not applicable.

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### **Carcinogenicity**

Not applicable.

### **Reproductive toxicity**

Not applicable.

### **Teratogenicity**

Not applicable.

### **Specific target organ toxicity – single exposure**

Not applicable.

### **Specific target organ toxicity – repeated exposure**

Not applicable.

### **Aspiration hazard**

Not applicable.

## 11.2 Further information

No information available.

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## **Section 12: Ecological information**

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### 12.1 Toxicity

No information available.

### 12.2 Persistence and degradability

No information available.

### 12.3 Bioaccumulative potential

No information available.

### 12.4 Mobility in soil

No information available.

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

No information available.

### 12.6 Other adverse effects

No information available.

### 12.7 Additional ecological information

An entry into the environment should be avoided.

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## **Section 13: Disposal considerations**

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### 13.1 Waste treatment methods

Residual product should be disposed of in accordance with EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste. Handle uncleaned containers like the product itself.

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## **Section 14: Transport information**

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### 14.1 UN-number

Not classified as dangerous good regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

### 14.2 Proper shipping name

Not applicable.

### 14.3 Class

Not applicable.

### 14.4 Packing group

Not applicable.

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- 14.5 Environmentally hazardous**  
None.
- 14.6 Special precautions for user**  
None.
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code**  
Not applicable.

### Section 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- EC legislation**  
None known
- National legislation**  
None known
- 15.2 Chemical safety assessment**  
For this product, a chemical safety assessment was not carried out.

### Section 16: Other information

Full text of H-Statements referred to under sections 3.2:

None

List of abbreviations:

°C	degree Celsius
ABEK	Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
EG/EU	European Union
EN	European Standard
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
NIOSH	National Institute for Occupational Safety and Health
PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)



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### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Section 8.2.2.2	Regulation and formulation adapted
Section 16	List of abbreviations added

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### Appendix 2 – Safety Data Sheet

Calibrators A – F	CAL
Cut-off Calibrator	CO-CAL
Positive Control	CON+
Negative Control	CON-

### Section 1: Identification of the substance/mixture and of the company

#### 1.1 Product identifier

Product name:

Calibrators A – F

Cut-off Calibrator

Positive Control

Negative Control

Symbol:

CAL

CO-CAL

CON+

CON-

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

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55543 Bad Kreuzbach

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E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

#### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

### Section 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (Regulation (EC) No. 1272/2008)

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** Skin sensitization (Category 1), H317

#### 2.2 Label elements

Pictogram:



Signal word:

GHS07

Warning

Hazard statements:

H317: May cause an allergic reaction.

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Precaution phrases: P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention.

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.

### 2.3 Other hazards

This mixture contains calibrator- and control material, which can be from human origin (e.g. serum or plasma) and is therefore considered as potentially infectious.

This mixture is not classified as PBT or vPvB.

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## Section 3: Composition/information on ingredients

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### 3.1 Substance

Not applicable.

### 3.2 Mixture

#### Hazardous ingredients according to Regulation (EC) No. 1272/2008:

Name: Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)  
 EC-No.: 911-418-6  
 CAS-No. 55965-84-9  
 Index-No.: 613-167-00-5  
 REACH registration No.: 01-2120764691-48-xxxx  
 Amount (w/w): < 0,01 %

Hazard class and category	Hazard statements	Specific Concentration Limits / M-factors
Acute Tox. 2	H330	-
Acute Tox. 2	H310	-
Acute Tox. 3	H301	-
Skin. Corr. 1C	H314	Skin Corr. 1C; H314: C ≥ 0,6 % Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6 %
Eye Dam. 1	H318	Eye Dam. 1; H318: C ≥ 0,6 % Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 %
Skin Sens. 1A	H317	Skin Sens. 1A; H317: C ≥ 0,0015 %
Aquatic Acute 1	H400	M = 100
Aquatic Chronic 1	H410	M = 100

#### Annotation:

The full text of H-statements is in section 16.

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## Section 4: First aid measures

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### 4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.  
 After skin contact: Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.  
 After eye contact: Rinse with plenty of water. Consult an ophthalmologist.  
 After swallowing: Induce vomiting when the affected person is not unconscious. Rinse mouth immediately and drink plenty of water. Consult physician.

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

No information available.

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

Treat symptomatically.

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## Section 5: Firefighting measures

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### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

None known.

### 5.2 Special hazards arising from the substance or measure

Not combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

### 5.3 Advice for firefighters

Special protective equipment for firefighters.

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

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## Section 6: Accidental release measures

---

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

#### 6.1.1 Advice for non-emergency personnel

Do not breathe vapours/aerosols. Avoid substance contact. Provide adequate ventilation. Evacuate the danger area. Follow emergency procedures. Consult an expert.

#### 6.1.2 Advice for emergency responders

Protective equipment see section 8.

### 6.2 Environmental precautions

Do not allow to enter into surface water, drains or soil.

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

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area

### 6.4 Reference to other sections

Indications about waste treatment see section 13.

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## Section 7: Handling and storage

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### 7.1 Precautions for safe handling

#### 7.1.1 Advice on safe handling

See labelling. When using do not eat, drink and smoke. Wash hands before breaks and after work. Used working clothes should not be worn outside the working area.

#### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

#### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct

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sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 12 (non-combustible liquids)

### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

## Section 8: Exposure controls/personal protection

### 8.1 Control parameters

No data available.

### 8.2 Exposure controls

#### 8.2.1 Engineering measures

Provide adequate ventilation.

#### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work. Draw up and observe protection program.

##### 8.2.2.1 Eye/Face protection

Eye glasses with side protection according EN 166 (EG), NISOH (US).

##### 8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile rubber or butyl rubber. The protective gloves to be used must comply with the specifications of Regulation (EU) 2016/425 and the related standard EN374.

##### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

##### 8.2.2.4 Respiratory protection

Not required if the product is used as intended. If there is a change in risk assessment full face mask with multipurpose combination filter type ABEK (EN 14387).

### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Form	liquid
Colour	yellow (Calibrators A – F, Cut-off Calibrator, Positive Control), colorless (Negative Control)
Odour	characteristic
Odour Treshold	Not applicable.
pH	6.7 – 6.9
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available.
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.

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Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	None
<b>9.2 Other data</b>	
No additional information.	

### Section 10: Stability and reactivity

- 10.1 Reactivity**  
See section 10.3.
- 10.2 Chemical stability**  
Recommended storage temperature: +2 to +8 °C.
- 10.3 Possibility of hazardous reactions**  
No information available.
- 10.4 Conditions to avoid**  
Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).
- 10.5 Incompatible materials**  
No information available
- 10.6 Hazardous decomposition products**  
No information available

### Section 11: Toxicological information

- 11.1 Information on toxicological effects**  
Mixture
- Acute oral toxicity**  
The mixture does not contain relevant substances.  
The mixture is not classified in acute oral toxicity.
- Acute inhalation toxicity**  
The mixture does not contain relevant substances.  
The mixture is not classified in acute inhalation toxicity.
- Acute dermal toxicity**  
The mixture does not contain relevant substances.  
The mixture is not classified in acute dermal toxicity.
- Skin corrosion/irritation**  
The mixture does not contain relevant substances.  
The mixture is not classified in acute corrosion/irritation.
- Serious eye damage/irritation**  
The mixture does not contain relevant substances.  
The mixture is not classified in serious eye damage/irritation.
- Skin sensitization**  
Relevant ingredients:
- |   |   |
|---|---|
| Substance:                                  | Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1) |
| Amount:                                     | < 0,01 %  |
| Classification of the substance: Category 1 |   |
| SCL (Category 1):                           | C ≥ 0,0015 %  |
- The mixture is classified in category 1 in skin sensitization.
- Germ cell mutagenicity**  
The mixture does not contain relevant substances.  
The mixture is not classified in germ cell mutagenicity.

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### **Carcinogenicity**

The mixture does not contain relevant substances.

The mixture is not classified in carcinogenicity.

### **Reproductive toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in reproductive toxicity.

### **Teratogenicity**

The mixture does not contain relevant substances.

The mixture is not classified in teratogenicity.

### **Specific target organ toxicity – single exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – single exposure.

### **Specific target organ toxicity – repeated exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – repeated exposure.

### **Aspiration hazard**

The mixture does not contain relevant substances.

The mixture is not classified in aspiration hazard.

## **11.2 Further information**

Quantitative data on the toxicity of this product is not available. Human sera are used to prepare this mixture. Although all sera used are tested negative for anti-HIV 1- and 2-Ab, HBsAg (hepatitis B virus surface antigen) and HCV, they must be considered potentially infectious. The mixture also contains components of animal origin. The usual precautions for handling chemicals must be considered.

## **Section 12: Ecological information**

Mixture

### **12.1 Toxicity**

Quantitative data on the toxicity of this mixture are not available.

### **12.2 Persistence and degradability**

The methods for determining the biological degradability are not applicable to inorganic substances.

### **12.3 Bioaccumulative potential**

No bioaccumulation expected.

### **12.4 Mobility in soil**

No information available.

### **12.5 Results of PBT- and vPvB-assessment**

None of the used substances meet the PBT/vPvB criteria of REACH, annex XIII.

### **12.6 Other adverse effects**

Do not allow to enter drains, waterways or soil.

### **12.7 Additional ecological information**

An entry into the environment should be avoided.

## **Section 13: Disposal considerations**

### **13.1 Waste treatment methods**

Residual product should be disposed of in accordance with EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste. Handle uncleaned containers like the product itself.

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### Section 14: Transport information

- 14.1 UN-number**  
Not classified as dangerous goods regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).
- 14.2 Proper shipping name**  
Not applicable.
- 14.3 Class**  
Not applicable.
- 14.4 Packing group**  
Not applicable.
- 14.5 Environmentally hazardous**  
None.
- 14.6 Special precautions for user**  
None.
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code**  
Not applicable. The product is only delivered and transported in packaging approved for traffic purposes.

### Section 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- EC legislation**  
Directive 2012/18/EU  
Employment restrictions:
- Does not apply.  
Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
- National legislation**  
Water hazard class (D):
- 0 – non-hazardous to water (AwSV)
- 15.2 Chemical safety assessment**  
For this product, a chemical safety assessment was not carried out.

### Section 16: Other information

Full text of H-Statements referred to under sections 3.2:

H301	Toxic if swallowed.
H330	Fatal if inhaled.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

List of abbreviations:

°C	degree Celsius
ABEK	Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)



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ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
CO	Carbon monoxide
CO <sub>2</sub>	Carbon dioxide
EG/EU	European Union
EN	European Standard
HBsAg	Hepatitis B virus surface antigen
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
NIOSH	National Institute for Occupational Safety and Health
PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
SCL	Specific concentration limit
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)

### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Section 2.1	Hazard class and category added
Section 3.2	Hazard class and category added; specific concentration limits and M-factors according legal classification added; annotation adapted
Section 8.2.2.2	Regulation and formulation adapted
Section 11.1	Skin sensitization actualized
Section 15	Regulation adapted
Section 16	List of abbreviations added

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### Appendix 3 – Safety Data Sheet

Sample Buffer, 5x conc.

SB 5x

#### Section 1: Identification of the substance/mixture and of the company

##### 1.1 Product identifier

Product name:

**Sample Buffer, 5x conc.**

Symbol:

SB 5x

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

Dr.-Karl-Aschoff-Straße 9

55543 Bad Kreuzbach

Germany

Tel. +49 (0) 671 – 920 650 – 90

Fax +49 (0) 671 – 920 650 – 91

E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

##### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

#### Section 2: Hazards identification

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

###### Classification (Regulation (EC) No. 1272/2008)

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** This product is not classified in accordance to EC regulation No. 1272/2008.

##### 2.2 Label elements

Pictogram: None

Signal word: None

Hazard statements: None

Precaution phrases: None

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.

##### 2.3 Other hazards

This mixture is not classified as PBT or vPvB.

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---

### Section 3: Composition/information on ingredients

---

#### 3.1 Substance

Not applicable.

#### 3.2 Mixture

Does not contain hazardous ingredients according to regulation (EC) No. 1272/2008.

---

### Section 4: First aid measures

---

#### 4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.

After skin contact: Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.

After eye contact: Rinse with plenty of water. Consult an ophthalmologist.

After swallowing: Induce vomiting when the affected person is not unconscious. Rinse mouth immediately and drink plenty of water. Consult physician.

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

No information available.

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

Treat symptomatically.

---

### Section 5: Firefighting measures

---

#### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

None known.

#### 5.2 Special hazards arising from the substance or measure

Not combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

Special protective equipment for firefighters.

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

---

### Section 6: Accidental release measures

---

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

##### 6.1.1 Advice for non-emergency personnel

Do not breathe vapours/aerosols. Avoid substance contact. Provide adequate ventilation. Evacuate the danger area. Follow emergency procedures. Consult an expert.

##### 6.1.2 Advice for emergency responders

Protective equipment see section 8.

#### 6.2 Environmental precautions

Do not allow to enter into surface water, drains or soil.

## Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

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

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area

### 6.4 Reference to other sections

Indications about waste treatment see section 13.

---

## Section 7: Handling and storage

---

### 7.1 Precautions for safe handling

#### 7.1.1 Advice on safe handling

See labelling. When using do not eat, drink and smoke. Thorough skin-cleansing after handling the product.

#### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

#### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 12 (non-combustible liquids)

### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

---

## Section 8: Exposure controls/personal protection

---

### 8.1 Control parameters

No data available.

### 8.2 Exposure controls

#### 8.2.1 Engineering measures

Provide adequate ventilation.

#### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work. Draw up and observe protection program.

##### 8.2.2.1 Eye/Face protection

Eye glasses with side protection according EN 166 (EG), NISOH (US).

##### 8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile rubber or butyl rubber. The protective gloves to be used must comply with the specifications of Regulation (EU) 2016/425 and the related standard EN374.

##### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

##### 8.2.2.4 Respiratory protection

Not required if the product is used as intended. If there is a change in risk assessment full face mask with multipurpose combination filter type ABEK (EN 14387).

### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

## Safety Data Sheet

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### Section 9: Physical and chemical properties

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

Form	liquid
Colour	yellow
Odour	odourless
Odour Treshold	Not applicable.
pH	7,4 – 7,6
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available.
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

#### 9.2 Other data

No additional information.

### Section 10: Stability and reactivity

#### 10.1 Reactivity

See section 10.3.

#### 10.2 Chemical stability

Recommended storage temperature: +2 to +8 °C.

#### 10.3 Possibility of hazardous reactions

Contact with acids releases toxic gases. Formation of nitrous gases possible.

#### 10.4 Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

#### 10.5 Incompatible materials

Acids, heavy metals.

#### 10.6 Hazardous decomposition products

Nitrous gases (see section 10.3)

### Section 11: Toxicological information

#### 11.1 Information on toxicological effects

Mixture

##### Acute oral toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute oral toxicity.

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### **Acute inhalation toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in acute inhalation toxicity.

### **Acute dermal toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in acute dermal toxicity.

### **Skin corrosion/irritation**

The mixture does not contain relevant substances.

The mixture is not classified in acute corrosion/irritation.

### **Serious eye damage/irritation**

The mixture does not contain relevant substances.

The mixture is not classified in serious eye damage/irritation.

### **Skin sensitization**

The mixture does not contain relevant substances.

The mixture is not classified in skin sensitization.

### **Germ cell mutagenicity**

The mixture does not contain relevant substances.

The mixture is not classified in germ cell mutagenicity.

### **Carcinogenicity**

The mixture does not contain relevant substances.

The mixture is not classified in carcinogenicity.

### **Reproductive toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in reproductive toxicity.

### **Teratogenicity**

The mixture does not contain relevant substances.

The mixture is not classified in teratogenicity.

### **Specific target organ toxicity – single exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – single exposure.

### **Specific target organ toxicity – repeated exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – repeated exposure.

### **Aspiration hazard**

The mixture does not contain relevant substances.

The mixture is not classified in aspiration hazard.

## 11.2 Further information

Quantitative data on the toxicity of this product are not available.

---

## **Section 12: Ecological information**

---

- Mixture
- 12.1 Toxicity**  
Quantitative data on the toxicity of this mixture are not available.
- 12.2 Persistence and degradability**  
No information available.
- 12.3 Bioaccumulative potential**  
No bioaccumulation expected.
- 12.4 Mobility in soil**  
No information available.
- 12.5 Results of PBT- and vPvB-assessment**  
None of the used substances meet the PBT/vPvB criteria of REACH, annex XIII.
- 12.6 Other adverse effects**  
Do not allow to enter drains, waterways or soil.
- 12.7 Additional ecological information**  
An entry into the environment should be avoided.

## Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

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### Section 13: Disposal considerations

#### 13.1 Waste treatment methods

Residual product should be disposed of in accordance with EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste. Handle uncleaned containers like the product itself.

### Section 14: Transport information

#### 14.1 UN-number

Not classified as dangerous goods regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

#### 14.2 Proper shipping name

Not applicable.

#### 14.3 Class

Not applicable.

#### 14.4 Packing group

Not applicable.

#### 14.5 Environmentally hazardous

None.

#### 14.6 Special precautions for user

None.

#### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code

Not applicable.

### Section 15: Regulatory information

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

##### EC legislation

Directive 2012/18/EU

Does not apply.

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

##### National legislation

Water hazard class (D):

0 – non-hazardous to water (AwSV)

#### 15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out.

### Section 16: Other information

Full text of H-Statements referred to under sections 3.2:

None

List of abbreviations:

°C degree Celsius

ABEK Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen

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	cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
CO	Carbon monoxide
CO <sub>2</sub>	Carbon dioxide
EG/EU	European Union
EN	European Standard
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
NIOSH	National Institute for Occupational Safety and Health
PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)

### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Section 8.2.2.2	Regulation and formulation adapted
Section 15	Regulation adapted
Section 16	List of abbreviations added



## Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

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### Appendix 4 – Safety Data Sheet

Wash Buffer, 50x conc.

WASHB 50x

#### Section 1: Identification of the substance/mixture and of the company

##### 1.1 Product identifier

Product name:

Symbol:

Wash Buffer, 50x conc.

WASHB 50x

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

Dr.-Karl-Aschoff-Straße 9

55543 Bad Kreuzbach

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Tel. +49 (0) 671 – 920 650 – 90

Fax +49 (0) 671 – 920 650 – 91

E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

##### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

#### Section 2: Hazards identification

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

###### Classification (Regulation (EC) No. 1272/2008)

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** Skin sensitization (Category 1), H317

##### 2.2 Label elements

Pictogram:



GHS07

Signal word: Warning

Hazard statements: H317: May cause an allergic reaction.

Precaution phrases: P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention.

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.

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### 2.3 Other hazards

This mixture is not classified as PBT or vPvB.

---

## Section 3: Composition/information on ingredients

---

### 3.1 Substance

Not applicable.

### 3.2 Mixture

#### Hazardous ingredients according to Regulation (EC) No. 1272/2008:

Name: Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)  
 EC-No.: 911-418-6  
 CAS-No.: 55965-84-9  
 Index-No.: 613-167-00-5  
 REACH registration No.: 01-2120764691-48-xxxx  
 Amount (w/w): < 0,01 %

Hazard class and category	Hazard statements	Specific Concentration Limits / M-factors
Acute Tox. 2	H330	-
Acute Tox. 2	H310	-
Acute Tox. 3	H301	-
Skin. Corr. 1C	H314	Skin Corr. 1C; H314: $C \geq 0,6 \%$ Skin Irrit. 2; H315: $0,06 \% \leq C < 0,6 \%$
Eye Dam. 1	H318	Eye Dam. 1; H318: $C \geq 0,6 \%$ Eye Irrit. 2; H319: $0,06 \% \leq C < 0,6 \%$
Skin Sens. 1A	H317	Skin Sens. 1A; H317: $C \geq 0,0015 \%$
Aquatic Acute 1	H400	M = 100
Aquatic Chronic 1	H410	M = 100

#### Annotation:

The full text of H-statements is in section 16.

---

## Section 4: First aid measures

---

### 4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.

After skin contact: Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.

After eye contact: Rinse with plenty of water. Consult an ophthalmologist.

After swallowing: Induce vomiting when the affected person is not unconscious. Rinse mouth immediately and drink plenty of water. Consult physician.

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

No information available.

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

Treat symptomatically.

## Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

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### Section 5: Firefighting measures

---

#### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

None known.

#### 5.2 Special hazards arising from the substance or measure

Not combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

Special protective equipment for firefighters.

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

---

### Section 6: Accidental release measures

---

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

##### 6.1.1 Advice for non-emergency personnel

Do not breathe vapours/aerosols. Avoid substance contact. Provide adequate ventilation. Evacuate the danger area. Follow emergency procedures. Consult an expert.

##### 6.1.2 Advice for emergency responders

Protective equipment see section 8.

#### 6.2 Environmental precautions

Do not allow to enter into surface water, drains or soil.

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

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area

#### 6.4 Reference to other sections

Indications about waste treatment see section 13.

---

### Section 7: Handling and storage

---

#### 7.1 Precautions for safe handling

##### 7.1.1 Advice on safe handling

See labelling. When using do not eat, drink and smoke. Wash hands before breaks and after work. Used working clothes should not be worn outside the working area.

##### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

##### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 12 (non-combustible liquids)

#### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

## Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

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### Section 8: Exposure controls/personal protection

#### 8.1 Control parameters

No data available.

#### 8.2 Exposure controls

##### 8.2.1 Engineering measures

Provide adequate ventilation.

##### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work.

Draw up and observe protection program.

##### 8.2.2.1 Eye/Face protection

Eye glasses with side protection according EN 166 (EG), NISOH (US).

##### 8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile rubber or butyl rubber. The protective gloves to be used must comply with the specifications of Regulation (EU) 2016/425 and the related standard EN374.

##### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

##### 8.2.2.4 Respiratory protection

Not required if the product is used as intended. If there is a change in risk assessment full face mask with multipurpose combination filter type ABEK (EN 14387).

#### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

### Section 9: Physical and chemical properties

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

Form	liquid
Colour	green
Odour	odorless
Odour Treshold	Not applicable.
pH	7,4 – 7,8
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available.
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	None

#### 9.2 Other data

No additional information.

## Safety Data Sheet

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---

### Section 10: Stability and reactivity

---

#### 10.1 Reactivity

See section 10.3.

#### 10.2 Chemical stability

Recommended storage temperature: +2 to +8 °C.

#### 10.3 Possibility of hazardous reactions

No information available.

#### 10.4 Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

#### 10.5 Incompatible materials

Acids, heavy metals.

#### 10.6 Hazardous decomposition products

No information available

---

### Section 11: Toxicological information

---

#### 11.1 Information on toxicological effects

Mixture

##### Acute oral toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute oral toxicity.

##### Acute inhalation toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute inhalation toxicity.

##### Acute dermal toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute dermal toxicity.

##### Skin corrosion/irritation

The mixture does not contain relevant substances.

The mixture is not classified in acute corrosion/irritation.

##### Serious eye damage/irritation

The mixture does not contain relevant substances.

The mixture is not classified in serious eye damage/irritation.

##### Skin sensitization

Relevant ingredients:

Substance:	Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)
Amount:	< 0,01 %
Classification of the substance:	Category 1
SCL (Category 1):	C ≥ 0,0015 %

The mixture is classified in category 1 in skin sensitization.

##### Germ cell mutagenicity

The mixture does not contain relevant substances.

The mixture is not classified in germ cell mutagenicity.

##### Carcinogenicity

The mixture does not contain relevant substances.

The mixture is not classified in carcinogenicity.

##### Reproductive toxicity

The mixture does not contain relevant substances.

The mixture is not classified in reproductive toxicity.

##### Teratogenicity

The mixture does not contain relevant substances.

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The mixture is not classified in teratogenicity.

### **Specific target organ toxicity – single exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – single exposure.

### **Specific target organ toxicity – repeated exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – repeated exposure.

### **Aspiration hazard**

The mixture does not contain relevant substances.

The mixture is not classified in aspiration hazard.

## 11.2 Further information

Quantitative data on the toxicity of this product are not available.

---

## **Section 12: Ecological information**

---

- Mixture
- 12.1 Toxicity**  
Quantitative data on the toxicity of this mixture are not available.
- 12.2 Persistence and degradability**  
No information available.
- 12.3 Bioaccumulative potential**  
No bioaccumulation expected.
- 12.4 Mobility in soil**  
No information available.
- 12.5 Results of PBT- and vPvB-assessment**  
None of the used substances meet the PBT/vPvB criteria of REACH, annex XIII.
- 12.6 Other adverse effects**  
Do not allow to enter drains, waterways or soil.
- 12.7 Additional ecological information**  
An entry into the environment should be avoided.

---

## **Section 13: Disposal considerations**

---

- 13.1 Waste treatment methods**  
Residual product should be disposed of in accordance with EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste. Handle uncleaned containers like the product itself.

---

## **Section 14: Transport information**

---

- 14.1 UN-number**  
Not classified as dangerous goods regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).
- 14.2 Proper shipping name**  
Not applicable.
- 14.3 Class**  
Not applicable.
- 14.4 Packing group**  
Not applicable.

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- 14.5 Environmentally hazardous**  
None.
- 14.6 Special precautions for user**  
None.
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code**  
Not applicable. The product is only delivered and transported in packaging approved for traffic purposes.

### Section 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- EC legislation**  
Directive 2012/18/EU  
Employment restrictions: Does not apply.  
Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
- National legislation**  
Water hazard class (D): 0 – non-hazardous to water (AwSV)
- 15.2 Chemical safety assessment**  
For this product, a chemical safety assessment was not carried out.

### Section 16: Other information

Full text of H-Statements referred to under sections 3.2:

H301	Toxic if swallowed.
H330	Fatal if inhaled.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

List of abbreviations:

°C	degree Celsius
ABEK	Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
CO	Carbon monoxide
CO <sub>2</sub>	Carbon dioxide
EG/EU	European Union
EN	European Standard
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M

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IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
NIOSH	National Institute for Occupational Safety and Health
PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
SCL	Specific concentration limit
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)

### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Section 2.1	Hazard class and category added
Section 3.2	Hazard class and category added; specific concentration limits and M-factors according legal classification added; annotation adapted
Section 8.2.2.2	Regulation and formulation adapted
Section 11.1	Skin sensitization actualized
Section 15	Regulation adapted
Section 16	Hazard statements according legal classification adapted; list of abbreviations added



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### Appendix 5 – Safety Data Sheet

Anti-Human IgA, IgG or IgM Conjugate

CONJ

#### Section 1: Identification of the substance/mixture and of the company

##### 1.1 Product identifier

Product name:

Symbol:

Anti-Human IgA, IgG or IgM Conjugate

CONJ

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

Dr.-Karl-Aschoff-Straße 9

55543 Bad Kreuzbach

Germany

Tel. +49 (0) 671 – 920 650 – 90

Fax +49 (0) 671 – 920 650 – 91

E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

##### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

#### Section 2: Hazards identification

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

###### Classification (Regulation (EC) No. 1272/2008)

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** Skin sensitization (Category 1), H317

##### 2.2 Label elements

Pictogram:



Signal word:

GHS07

Hazard statements:

Warning

Precaution phrases:

H317: May cause an allergic reaction.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

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

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.

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### 2.3 Other hazards

This mixture contains material of human origin and is therefore considered as potentially infectious.

This mixture is not classified as PBT or vPvB.

---

## Section 3: Composition/information on ingredients

---

### 3.1 Substance

Not applicable.

### 3.2 Mixture

#### Hazardous ingredients according to Regulation (EC) No. 1272/2008:

Name: Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)  
 EC-No.: 911-418-6  
 CAS-No. 55965-84-9  
 Index-No.: 613-167-00-5  
 REACH registration No.: 01-2120764691-48-xxxx  
 Amount (w/w): < 0,01 %

Hazard class and category	Hazard statements	Specific Concentration Limits / M-factors
Acute Tox. 2	H330	-
Acute Tox. 2	H310	-
Acute Tox. 3	H301	-
Skin. Corr. 1C	H314	Skin Corr. 1C; H314: C ≥ 0,6 % Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6 %
Eye Dam. 1	H318	Eye Dam. 1; H318: C ≥ 0,6 % Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 %
Skin Sens. 1A	H317	Skin Sens. 1A; H317: C ≥ 0,0015 %
Aquatic Acute 1	H400	M = 100
Aquatic Chronic 1	H410	M = 100

#### Annotation:

The full text of H-statements is in section 16.

---

## Section 4: First aid measures

---

### 4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.

After skin contact: Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.

After eye contact: Rinse with plenty of water. Consult an ophthalmologist.

After swallowing: Induce vomiting when the affected person is not unconscious. Rinse mouth immediately and drink plenty of water. Consult physician.

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

No information available.

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

Treat symptomatically.

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### Section 5: Firefighting measures

---

#### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

None known.

#### 5.2 Special hazards arising from the substance or measure

Not combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

Special protective equipment for firefighters.

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

---

### Section 6: Accidental release measures

---

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

##### 6.1.1 Advice for non-emergency personnel

Do not breathe vapours/aerosols. Avoid substance contact. Provide adequate ventilation. Evacuate the danger area. Follow emergency procedures. Consult an expert.

##### 6.1.2 Advice for emergency responders

Protective equipment see section 8.

#### 6.2 Environmental precautions

Do not allow to enter into surface water, drains or soil.

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

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area

#### 6.4 Reference to other sections

Indications about waste treatment see section 13.

---

### Section 7: Handling and storage

---

#### 7.1 Precautions for safe handling

##### 7.1.1 Advice on safe handling

See labelling. When using do not eat, drink and smoke. Wash hands before breaks and after work. Used working clothes should not be worn outside the working area.

##### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

##### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 12 (non-combustible liquids)

#### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

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### Section 8: Exposure controls/personal protection

#### 8.1 Control parameters

No data available.

#### 8.2 Exposure controls

##### 8.2.1 Engineering measures

Provide adequate ventilation.

##### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work.

Draw up and observe protection program.

##### 8.2.2.1 Eye/Face protection

Eye glasses with side protection according EN 166 (EG), NISOH (US).

##### 8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile rubber or butyl rubber. The protective gloves to be used must comply with the specifications of Regulation (EU) 2016/425 and the related standard EN374.

##### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

##### 8.2.2.4 Respiratory protection

Not required if the product is used as intended. If there is a change in risk assessment full face mask with multipurpose combination filter type ABEK (EN 14387).

#### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

### Section 9: Physical and chemical properties

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

Form	liquid
Colour	red (IgA), blue (IgG), green (IgM)
Odour	characteristic
Odour Treshold	Not applicable.
pH	6,7 – 6,9
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available.
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	None

#### 9.2 Other data

No additional information.

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### Section 10: Stability and reactivity

#### 10.1 Reactivity

See section 10.3.

#### 10.2 Chemical stability

Recommended storage temperature: +2 to +8 °C.

#### 10.3 Possibility of hazardous reactions

No information available.

#### 10.4 Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

#### 10.5 Incompatible materials

No information available

#### 10.6 Hazardous decomposition products

No information available

### Section 11: Toxicological information

#### 11.1 Information on toxicological effects

Mixture

##### Acute oral toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute oral toxicity.

##### Acute inhalation toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute inhalation toxicity.

##### Acute dermal toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute dermal toxicity.

##### Skin corrosion/irritation

The mixture does not contain relevant substances.

The mixture is not classified in acute corrosion/irritation.

##### Serious eye damage/irritation

The mixture does not contain relevant substances.

The mixture is not classified in serious eye damage/irritation.

##### Skin sensitization

Relevant ingredients:

Substance:	Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)
Amount:	< 0,01 %
Classification of the substance:	Category 1
SCL (Category 1):	C ≥ 0,0015 %

The mixture is classified in category 1 in skin sensitization.

##### Germ cell mutagenicity

The mixture does not contain relevant substances.

The mixture is not classified in germ cell mutagenicity.

##### Carcinogenicity

The mixture does not contain relevant substances.

The mixture is not classified in carcinogenicity.

##### Reproductive toxicity

The mixture does not contain relevant substances.

The mixture is not classified in reproductive toxicity.

##### Teratogenicity

The mixture does not contain relevant substances.

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The mixture is not classified in teratogenicity.

### **Specific target organ toxicity – single exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – single exposure.

### **Specific target organ toxicity – repeated exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – repeated exposure.

### **Aspiration hazard**

The mixture does not contain relevant substances.

The mixture is not classified in aspiration hazard.

## 11.2 Further information

Quantitative data on the toxicity of this product is not available. Human sera are used to prepare this mixture. Although all sera used are tested negative for anti-HIV 1- and 2-Ab, HBsAg (hepatitis B virus surface antigen) and HCV, they must be considered potentially infectious. The mixture also contains components of animal origin. The usual precautions for handling chemicals must be considered.

---

## **Section 12: Ecological information**

---

- Mixture
- 12.1 **Toxicity**  
Quantitative data on the toxicity of this mixture are not available.
- 12.2 **Persistence and degradability**  
The methods for determining the biological degradability are not applicable to inorganic substances.
- 12.3 **Bioaccumulative potential**  
No bioaccumulation expected.
- 12.4 **Mobility in soil**  
No information available.
- 12.5 **Results of PBT- and vPvB-assessment**  
None of the used substances meet the PBT/vPvB criteria of REACH, annex XIII.
- 12.6 **Other adverse effects**  
Do not allow to enter drains, waterways or soil.
- 12.7 **Additional ecological information**  
An entry into the environment should be avoided.

---

## **Section 13: Disposal considerations**

---

- 13.1 **Waste treatment methods**  
Residual product should be disposed of in accordance with EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste. Handle uncleaned containers like the product itself.

---

## **Section 14: Transport information**

---

- 14.1 **UN-number**  
Not classified as dangerous goods regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).
- 14.2 **Proper shipping name**  
Not applicable.

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- 14.3 Class**  
Not applicable.
- 14.4 Packing group**  
Not applicable.
- 14.5 Environmentally hazardous**  
None.
- 14.6 Special precautions for user**  
None.
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code**  
Not applicable. The product is only delivered and transported in packaging approved for traffic purposes.

### Section 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- EC legislation**  
Directive 2012/18/EU  
Employment restrictions: Does not apply.  
Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
- National legislation**  
Water hazard class (D): 0 – non-hazardous to water (AwSV)
- 15.2 Chemical safety assessment**  
For this product, a chemical safety assessment was not carried out.

### Section 16: Other information

#### Full text of H-Statements referred to under sections 3.2:

H301	Toxic if swallowed.
H330	Fatal if inhaled.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

#### List of abbreviations:

°C	degree Celsius
ABEK	Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
CO	Carbon monoxide
CO <sub>2</sub>	Carbon dioxide
EG/EU	European Union
EN	European Standard
HBsAg	Hepatitis B virus surface antigen

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HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
NIOSH	National Institute for Occupational Safety and Health
PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
SCL	Specific concentration limit
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)

### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Section 2.1	Hazard class and category added
Section 3.2	Hazard class and category added; specific concentration limits and M-factors according legal classification added; annotation adapted
Section 8.2.2.2	Regulation and formulation adapted
Section 9	Color for IgA adapted
Section 11.1	Skin sensitization actualized
Section 15	Regulation adapted
Section 16	Hazard statements according legal classification adapted; list of abbreviations added



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### Appendix 6 – Safety Data Sheet

**Substrate**

**SUB**

#### Section 1: Identification of the substance/mixture and of the company

##### 1.1 Product identifier

Product name:

**TMB ELISA Substrate**

Symbol:

**SUB**

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

Dr.-Karl-Aschoff-Straße 9

55543 Bad Kreuzbach

Germany

Tel. +49 (0) 671 – 920 650 – 90

Fax +49 (0) 671 – 920 650 – 91

E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

##### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

#### Section 2: Hazards identification

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

###### Classification (Regulation (EC) No. 1272/2008)

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** This product is not classified in accordance to EC regulation No. 1272/2008 amended by (EU) 2018/669.

##### 2.2 Label elements

Pictogram: None

Signal word: None

Hazard statements: None

Precaution phrases: None

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.

##### 2.3 Other hazards

This mixture is not classified as PBT or vPvB.

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### Section 3: Composition/information on ingredients

---

#### 3.1 Substance

Not applicable.

#### 3.2 Mixture

Buffer solution with TMB and hydrogen peroxide as an oxidant. The concentrations of hazardous ingredients according to Regulation (EC) No. 1272/2008, amended by Regulation (EU) 2018/669, are below the legal concentration limits.

The full text of H-statements is in section 16.

---

### Section 4: First aid measures

---

#### 4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.

After skin contact: Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.

After eye contact: Rinse with plenty of water. Consult an ophthalmologist.

After swallowing: Induce vomiting when the affected person is not unconscious. Rinse mouth immediately and drink plenty of water. Consult physician.

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

No information available.

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

Treat symptomatically.

---

### Section 5: Firefighting measures

---

#### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

None known.

#### 5.2 Special hazards arising from the substance or measure

Not combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

Special protective equipment for firefighters.

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

---

### Section 6: Accidental release measures

---

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

Use personal protective equipment. Provide adequate ventilation.

#### 6.2 Environmental precautions

Do not allow to enter into surface water, drains or soil.

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

Wipe up and place in appropriate containers for disposal.

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### 6.4 Reference to other sections

Personal protective equipment see section 8.

Indications about waste treatment see section 13.

---

## Section 7: Handling and storage

---

### 7.1 Precautions for safe handling

#### 7.1.1 Advice on safe handling

See labelling. When using do not eat, drink and smoke. Thorough skin-cleansing after handling the product.

#### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

#### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 12 (non-combustible liquids)

### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

---

## Section 8: Exposure controls/personal protection

---

### 8.1 Control parameters

Does not contain substances above concentration limits fixing an occupational exposure limit.

### 8.2 Exposure controls

The usual precautions for handling chemicals must be observed.

#### 8.2.1 Engineering measures

Provide adequate ventilation.

#### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work. Draw up and observe protection programme.

##### 8.2.2.1 Eye/Face protection

Eye glasses with side protection according EN 166 (EG), NISOH (US).

##### 8.2.2.2 Skin protection/Hand protection

When handling chemical agents, only chemical protective gloves with a CE mark including a four-digit test number may be worn. Take recovery periods for skin regeneration.

Suitable materials even with longer, direct contact (recommended: at least protection index 6, corresponding to > 480 minutes permeation time according to EN 374):

Laboratory protective gloves made of nitrile (material thickness min. 0.28 mm) or natural latex (material thickness min. 0.22 mm).

Additional information: The information is based on test results, literature and information from glove manufacturers or is derived from similar substances by analogy. It should be noted that, due to the many influencing factors (e.g. temperature), the service life of a chemical protective glove in practice can be significantly shorter than the permeation time determined according to EN 374. If there are signs of wear, the glove must be changed.

##### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

##### 8.2.2.4 Respiratory protection

Not required if the product is used as intended.

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### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colorless to slightly yellowish
Odour	characteristic
Odour Treshold	No information available.
pH	3,5 – 4,0
Melting point	No information available.
Boiling point	101°C
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,011 g/ml
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	None

### 9.2 Other data

No additional information.

## Section 10: Stability and reactivity

### 10.1 Reactivity

No information available.

### 10.2 Chemical stability

Stable under stated storage conditions (see section 7.2).

### 10.3 Possibility of hazardous reactions

With proper handling and storage, no hazardous reactions occur.

### 10.4 Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

### 10.5 Incompatible materials

Strong oxidizing agents, metals and their salts (will not cause a dangerous reaction, but destroys the quality of the products).

### 10.6 Hazardous decomposition products

No known hazardous decomposition products. In case of fire: see section 5.

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### Section 11: Toxicological information

---

#### 11.1 Information on toxicological effects

Mixture

##### **Acute oral toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in acute oral toxicity.

##### **Acute inhalation toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in acute inhalation toxicity.

##### **Acute dermal toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in acute dermal toxicity.

##### **Skin corrosion/irritation**

The mixture does not contain relevant substances.

The mixture is not classified in acute corrosion/irritation.

##### **Serious eye damage/irritation**

The mixture does not contain relevant substances.

The mixture is not classified in serious eye damage/irritation.

##### **Skin sensitization**

The mixture does not contain relevant substances.

The mixture is not classified in skin sensitization.

##### **Germ cell mutagenicity**

The mixture does not contain relevant substances.

The mixture is not classified in germ cell mutagenicity.

##### **Carcinogenicity**

The mixture does not contain relevant substances.

The mixture is not classified in carcinogenicity.

##### **Reproductive toxicity**

The mixture does not contain relevant substances.

The mixture is not classified in reproductive toxicity.

##### **Teratogenicity**

The mixture does not contain relevant substances.

The mixture is not classified in teratogenicity.

##### **Specific target organ toxicity – single exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – single exposure.

##### **Specific target organ toxicity – repeated exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – repeated exposure.

##### **Aspiration hazard**

The mixture does not contain relevant substances.

The mixture is not classified in aspiration hazard.

#### 11.2 Further information

Quantitative data on the toxicity of this product are not available.

---

### Section 12: Ecological information

---

Mixture

#### 12.1 Toxicity

Quantitative data on the toxicity of this mixture are not available.

#### 12.2 Persistence and degradability

No information available.

#### 12.3 Bioaccumulative potential

No bioaccumulation expected.

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### 12.4 Mobility in soil

No information available.

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

None of the used substances meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6 Other adverse effects

Do not allow to enter drains, waterways or soil.

### 12.7 Additional ecological information

An entry into the environment should be avoided.

## Section 13: Disposal considerations

### 13.1 Waste treatment methods

Residual product should be disposed of in accordance with EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste. Handle uncleaned containers like the product itself.

## Section 14: Transport information

### 14.1 UN-number

Not classified as dangerous goods regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

### 14.2 Proper shipping name

Not applicable.

### 14.3 Class

Not applicable.

### 14.4 Packing group

Not applicable.

### 14.5 Environmentally hazardous

None.

### 14.6 Special precautions for user

None.

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code

Not applicable.

## Section 15: Regulatory information

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

#### EC legislation

Directive 2012/18/EU

Does not apply.

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

#### National legislation

Water hazard class (D):

0 – non-hazardous to water (AwSV)

### 15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out.

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### Section 16: Other information

#### Full text of H-Statements referred to under sections 3.2:

None

#### List of abbreviations:

°C	degree Celsius
ABEK	Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
CO	Carbon monoxide
CO <sub>2</sub>	Carbon dioxide
EG/EU	European Union
EN	European Standard
g	gram
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
ml	milliliters
NIOSH	National Institute for Occupational Safety and Health
PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)

#### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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#### Changes to the prior version:

Section 15	Regulation adapted
Section 16	List of abbreviations added

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### Appendix 7 – Safety Data Sheet

**Stop Solution**

**STOP**

#### Section 1: Identification of the substance/mixture and of the company

##### 1.1 Product identifier

Product name:

Symbol:

**Stop Solution**

**STOP**

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

Dr.-Karl-Aschoff-Straße 9

55543 Bad Kreuzbach

Germany

Tel. +49 (0) 671 – 920 650 – 90

Fax +49 (0) 671 – 920 650 – 91

E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

##### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

#### Section 2: Hazards identification

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

###### Classification (Regulation (EC) No. 1272/2008)

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** Corrosive to metal (Category 1), H290

##### 2.2 Label elements

**Pictogram:** None.

**Signal word:** Warning

**Hazard statements:** H290: May be corrosive to metals.

**Precaution phrases:** P390: Absorb spillage to prevent material damage.

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.

##### 2.3 Other hazards

This mixture is not classified as PBT or vPvB.



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### Section 3: Composition/information on ingredients

#### 3.1 Substance

Not applicable.

#### 3.2 Mixture

##### Hazardous ingredients according to Regulation (EC) No. 1272/2008:

Name: Hydrochloric acid ... %  
 EC-No.: 231-595-7  
 CAS-No. 7647-01-0  
 Index-No.: 017-002-01-X  
 REACH registration No.: 01-2119484862-27-xxxx  
 Amount (w/w): < 3,0 %

Hazard class and category	Hazard statements	Specific Concentration Limits / M-factors
Met. Corr. 1	H290	Met. Corr. 1; H290: C ≥ 0,1%
Skin Corr. 1B	H314	Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 %
Eye Dam. 1	H318	Eye Dam. 1; H318: C ≥ 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %
STOT SE 3	H335	STOT SE 3; H335: C ≥ 10 %

##### Annotation:

The full text of H-statements is in section 16.

### Section 4: First aid measures

#### 4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.  
 After skin contact: Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.  
 After eye contact: Rinse with plenty of water. Consult an ophthalmologist.  
 After swallowing: Induce vomiting when the affected person is not unconscious. Rinse mouth immediately and drink plenty of water. Consult physician.

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

Irritations.

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

Treat symptomatically.

### Section 5: Firefighting measures

#### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

Full water jet.

#### 5.2 Special hazards arising from the substance or measure

Not combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

Special protective equipment for firefighters.

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In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

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### Section 6: Accidental release measures

---

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

##### 6.1.1 Advice for non-emergency personnel

Do not breathe vapours/aerosols. Avoid substance contact. Provide adequate ventilation. Evacuate the danger area. Follow emergency procedures. Consult an expert.

##### 6.1.2 Advice for emergency responders

Protective equipment see section 8.

#### 6.2 Environmental precautions

Do not allow to enter into surface water, drains or soil.

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

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area

#### 6.4 Reference to other sections

Indications about waste treatment see section 13.

---

### Section 7: Handling and storage

---

#### 7.1 Precautions for safe handling

##### 7.1.1 Advice on safe handling

See labelling. When using do not eat, drink and smoke. Wash hands before breaks and after work. Used working clothes should not be worn outside the working area.

##### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

##### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 12 (non-combustible liquids)

#### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

---

### Section 8: Exposure controls/personal protection

---

#### 8.1 Control parameters

No data available.

#### 8.2 Exposure controls

##### 8.2.1 Engineering measures

Provide adequate ventilation.

##### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work. Draw up and observe protection program.

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### 8.2.2.1 Eye/Face protection

Eye glasses with side protection according EN 166 (EG), NISOH (US).

### 8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile rubber or butyl rubber. The protective gloves to be used must comply with the specifications of Regulation (EU) 2016/425 and the related standard EN374.

### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

### 8.2.2.4 Respiratory protection

Not required if the product is used as intended. If there is a change in risk assessment full face mask with multipurpose combination filter type ABEK (EN 14387).

### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

---

## Section 9: Physical and chemical properties

---

### 9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colorless
Odour	odorless
Odour Treshold	Not applicable.
pH	2,6 – 3,2
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,002g/cm <sup>3</sup> at 20°C
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	None

### 9.2 Other data

No additional information.

---

## Section 10: Stability and reactivity

---

### 10.1 Reactivity

Corrosive to metals.

### 10.2 Chemical stability

Recommended storage temperature: +2 to +8 °C.

### 10.3 Possibility of hazardous reactions

No information available.

### 10.4 Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

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### 10.5 Incompatible materials

Different metals and metal alloys.

### 10.6 Hazardous decomposition products

Hazardous combustion products see section 5.

## Section 11: Toxicological information

### 11.1 Information on toxicological effects

Mixture

#### Acute oral toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute oral toxicity.

#### Acute inhalation toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute inhalation toxicity.

#### Acute dermal toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute dermal toxicity.

#### Skin corrosion/irritation

Relevant ingredients:

Substance:	Hydrochloric acid ... %
Amount:	< 3,0 %
Classification of the substance:	Category 1
Classification of the mixture:	not summated
SCL (Category 1):	C ≥ 25 %
(Category 2):	10 % ≤ C < 25 %

The mixture is not classified in acute corrosion/irritation.

#### Serious eye damage/irritation

Relevant ingredients:

Substance:	Hydrochloric acid ... %
Amount:	< 3,0 %
Classification of the substance:	Category 1
Classification of the mixture:	not summated
SCL (Category 1):	C ≥ 25 %
(Category 2):	10 % ≤ C < 25 %

The mixture is not classified in serious eye damage/irritation.

#### Skin sensitization

The mixture does not contain relevant substances.

The mixture is not classified in skin sensitization.

#### Germ cell mutagenicity

The mixture does not contain relevant substances.

The mixture is not classified in germ cell mutagenicity.

#### Carcinogenicity

The mixture does not contain relevant substances.

The mixture is not classified in carcinogenicity.

#### Reproductive toxicity

The mixture does not contain relevant substances.

The mixture is not classified in reproductive toxicity.

#### Teratogenicity

The mixture does not contain relevant substances.

The mixture is not classified in teratogenicity.

#### Specific target organ toxicity – single exposure

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – single exposure.

#### Specific target organ toxicity – repeated exposure

The mixture does not contain relevant substances.

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The mixture is not classified in specific target organ toxicity – repeated exposure.

### **Aspiration hazard**

The mixture does not contain relevant substances.

The mixture is not classified in aspiration hazard.

## 11.2 Further information

Quantitative data on the toxicity of this product are not available.

---

## **Section 12: Ecological information**

---

Mixture

### 12.1 Toxicity

According to 1272/2008/EG: Not classified as hazardous to water.

### 12.2 Persistence and degradability

The substance is not biodegradable.

The methods for determining the biological degradability are not applicable to inorganic substances.

### 12.3 Bioaccumulative potential

No bioaccumulation expected.

### 12.4 Mobility in soil

No information available.

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

None of the used substances meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6 Other adverse effects

Do not allow to enter drains, waterways or soil.

### 12.7 Additional ecological information

An entry into the environment should be avoided.

---

## **Section 13: Disposal considerations**

---

### 13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste and in accordance with local/regional/national/international regulations like 2008/98/EG.

#### **Sewage disposal-relevant information**

Do not empty into drains.

#### **Waste treatment of containers/packages**

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

---

## **Section 14: Transport information**

---

### 14.1 UN-number

Not classified as dangerous goods regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

### 14.2 Proper shipping name

Not applicable.

### 14.3 Class

Not applicable.

### 14.4 Packing group

Not applicable.

### 14.5 Environmentally hazardous

None.

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### 14.6 Special precautions for user

None.

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code

Not applicable. The product is only delivered and transported in packaging approved for traffic purposes.

## Section 15: Regulatory information

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

#### EC legislation

Directive 2012/18/EU

Does not apply.

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

#### National legislation

Water hazard class (D):

0 – non-hazardous to water (AwSV)

### 15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out.

## Section 16: Other information

#### Full text of H-Statements referred to under sections 3.2:

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

#### List of abbreviations:

°C	degree Celsius
ABEK	Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
cm	centimeter
CO	Carbon monoxide
CO <sub>2</sub>	Carbon dioxide
EG/EU	European Union
EN	European Standard
g	gram
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
NIOSH	National Institute for Occupational Safety and Health

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PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
SCL	Specific concentration limit
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)

### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Section 2.1	Hazard class and category added
Section 3.2	Hazard class and category added; specific concentration limits and M-factors according legal classification added; annotation adapted
Section 8.2.2.2	Regulation and formulation adapted
Section 11.1	Skin corrosion / irritation and serious eye damage / irritation actualized
Section 15	Regulation adapted
Section 16	Hazard statements according legal classification adapted; list of abbreviations added

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### Appendix 8 – Safety Data Sheet

Recovery

RC

#### Section 1: Identification of the substance/mixture and of the company

##### 1.1 Product identifier

Product name:

Symbol:

Recovery

RC

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

This enzyme immunoassay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics. This in vitro diagnostic is for serum and plasma. The assay should not be performed by anyone other than a professional who is familiar with in vitro diagnostic methods. It is not suitable for personal or for veterinary use. The reagents should not be used for purposes other than those specified.

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

AIDA GmbH

Dr.-Karl-Aschoff-Straße 9

55543 Bad Kreuzbach

Germany

Tel. +49 (0) 671 – 920 650 – 90

Fax +49 (0) 671 – 920 650 – 91

E-Mail info@aida-diagnostics.com

www.aida-diagnostics.com

##### 1.4 Emergency telephone number

Manufacturer: +49 (0) 671 – 920 650 – 90 (Monday to Friday, 8:30 am to 4:00 pm)

Poison Control Center: +49 (0) 228 – 19 240 (German and English)

#### Section 2: Hazards identification

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

**Classification (Regulation (EC) No. 1272/2008)**

**Product:** This product is not classified in accordance to EC regulation No. 1272/2008.

**Substance/Mixtures:** Skin sensitization (Category 1), H317

##### 2.2 Label elements

Pictogram:



GHS07

Signal word: Warning

Hazard statements: H317: May cause an allergic reaction.

Precaution phrases: P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention.

This product does not need to be labelled in accordance to EC directives or respective national laws.

**Note:** According to EU Regulation (EC) 1272/2008, Article 1 (5) d), IVDs within the meaning of Directive 98/79 / EC are exempted from the labeling requirement.



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### 2.3 Other hazards

This mixture is not classified as PBT or vPvB.

---

## Section 3: Composition/information on ingredients

---

### 3.1 Substance

Not applicable.

### 3.2 Mixture

#### Hazardous ingredients according to Regulation (EC) No. 1272/2008:

Name: Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)  
 EC-No.: 911-418-6  
 CAS-No.: 55965-84-9  
 Index-No.: 613-167-00-5  
 REACH registration No.: 01-2120764691-48-xxxx  
 Amount (w/w): < 0,01 %

Hazard class and category	Hazard statements	Specific Concentration Limits / M-factors
Acute Tox. 2	H330	-
Acute Tox. 2	H310	-
Acute Tox. 3	H301	-
Skin. Corr. 1C	H314	Skin Corr. 1C; H314: $C \geq 0,6 \%$ Skin Irrit. 2; H315: $0,06 \% \leq C < 0,6 \%$
Eye Dam. 1	H318	Eye Dam. 1; H318: $C \geq 0,6 \%$ Eye Irrit. 2; H319: $0,06 \% \leq C < 0,6 \%$
Skin Sens. 1A	H317	Skin Sens. 1A; H317: $C \geq 0,0015 \%$
Aquatic Acute 1	H400	M = 100
Aquatic Chronic 1	H410	M = 100

#### Annotation:

The full text of H-statements is in section 16.

---

## Section 4: First aid measures

---

### 4.1 Description of first aid measures

After inhalation: Fresh air. Consult physician if feeling unwell.

After skin contact: Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.

After eye contact: Rinse with plenty of water. Consult an ophthalmologist.

After swallowing: Induce vomiting when the affected person is not unconscious. Rinse mouth immediately and drink plenty of water. Consult physician.

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

No information available.

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

Treat symptomatically.

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### Section 5: Firefighting measures

---

#### 5.1 Extinguishing media

*Suitable extinguishing media*

Use an extinguishing agent suitable for the surrounding fire.

*Unsuitable extinguishing media.*

None known.

#### 5.2 Special hazards arising from the substance or measure

Not combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

#### 5.3 Advice for firefighters

Special protective equipment for firefighters.

In the event of fire, wear self-contained breathing apparatus. Avoid skin contact by maintaining a safe distance or wearing suitable protective clothing. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

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### Section 6: Accidental release measures

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

##### 6.1.1 Advice for non-emergency personnel

Do not breathe vapours/aerosols. Avoid substance contact. Provide adequate ventilation. Evacuate the danger area. Follow emergency procedures. Consult an expert.

##### 6.1.2 Advice for emergency responders

Protective equipment see section 8.

#### 6.2 Environmental precautions

Do not allow to enter into surface water, drains or soil.

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

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area

#### 6.4 Reference to other sections

Indications about waste treatment see section 13.

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### Section 7: Handling and storage

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#### 7.1 Precautions for safe handling

##### 7.1.1 Advice on safe handling

See labelling. When using do not eat, drink and smoke. Wash hands before breaks and after work. Used working clothes should not be worn outside the working area.

##### 7.1.2 Hygiene measures

Remove contaminated clothing. Preventive skin protection. Wash hands at the end of the working period.

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

##### Storage conditions:

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Do not store in unlabeled containers.

Store at +2°C to +8°C.

Storage class: 12 (non-combustible liquids)

#### 7.3 Specific end use(s)

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

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### Section 8: Exposure controls/personal protection

#### 8.1 Control parameters

No data available.

#### 8.2 Exposure controls

##### 8.2.1 Engineering measures

Provide adequate ventilation.

##### 8.2.2 Individual protection measures

When using do not eat, drink and smoke. Wash hands and face before breaks and after work.

Draw up and observe protection program.

##### 8.2.2.1 Eye/Face protection

Eye glasses with side protection according EN 166 (EG), NISOH (US).

##### 8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile rubber or butyl rubber. The protective gloves to be used must comply with the specifications of Regulation (EU) 2016/425 and the related standard EN374.

##### 8.2.2.3 Body protection

Personal protective equipment for handling chemical hazardous substances are sufficient (according to EN 14605).

##### 8.2.2.4 Respiratory protection

Not required if the product is used as intended. If there is a change in risk assessment full face mask with multipurpose combination filter type ABEK (EN 14387).

#### 8.2.3 Environmental exposure controls

Do not allow to enter drains, waterways or soil.

### Section 9: Physical and chemical properties

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

Form	liquid
Colour	yellow
Odour	characteristic
Odour Treshold	Not applicable.
pH	6,7 – 6,9
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available.
Water solubility	soluble
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	None

#### 9.2 Other data

No additional information.

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### Section 10: Stability and reactivity

#### 10.1 Reactivity

See section 10.3.

#### 10.2 Chemical stability

Recommended storage temperature: +2 to +8 °C.

#### 10.3 Possibility of hazardous reactions

No information available.

#### 10.4 Conditions to avoid

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

#### 10.5 Incompatible materials

No information available

#### 10.6 Hazardous decomposition products

No information available

### Section 11: Toxicological information

#### 11.1 Information on toxicological effects

Mixture

##### Acute oral toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute oral toxicity.

##### Acute inhalation toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute inhalation toxicity.

##### Acute dermal toxicity

The mixture does not contain relevant substances.

The mixture is not classified in acute dermal toxicity.

##### Skin corrosion/irritation

The mixture does not contain relevant substances.

The mixture is not classified in acute corrosion/irritation.

##### Serious eye damage/irritation

The mixture does not contain relevant substances.

The mixture is not classified in serious eye damage/irritation.

##### Skin sensitization

Relevant ingredients:

Substance:	Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)
Amount:	< 0,01 %
Classification of the substance:	Category 1
SCL (Category 1):	C ≥ 0,0015 %

The mixture is classified in category 1 in skin sensitization.

##### Germ cell mutagenicity

The mixture does not contain relevant substances.

The mixture is not classified in germ cell mutagenicity.

##### Carcinogenicity

The mixture does not contain relevant substances.

The mixture is not classified in carcinogenicity.

##### Reproductive toxicity

The mixture does not contain relevant substances.

The mixture is not classified in reproductive toxicity.

##### Teratogenicity

The mixture does not contain relevant substances.

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The mixture is not classified in teratogenicity.

### **Specific target organ toxicity – single exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – single exposure.

### **Specific target organ toxicity – repeated exposure**

The mixture does not contain relevant substances.

The mixture is not classified in specific target organ toxicity – repeated exposure.

### **Aspiration hazard**

The mixture does not contain relevant substances.

The mixture is not classified in aspiration hazard.

## 11.2 Further information

Quantitative data on the toxicity of this product are not available.

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## **Section 12: Ecological information**

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Mixture

### 12.1 Toxicity

Quantitative data on the toxicity of this mixture are not available.

### 12.2 Persistence and degradability

The methods for determining the biological degradability are not applicable to inorganic substances.

### 12.3 Bioaccumulative potential

No bioaccumulation expected.

### 12.4 Mobility in soil

No information available.

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

None of the used substances meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6 Other adverse effects

Do not allow to enter drains, waterways or soil.

### 12.7 Additional ecological information

An entry into the environment should be avoided.

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## **Section 13: Disposal considerations**

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### 13.1 Waste treatment methods

Residual product should be disposed of in accordance with EC and national directives, e.g. 2008/98/EG. Do not decant residual product and/or mix with other waste. Handle uncleaned containers like the product itself.

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## **Section 14: Transport information**

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### 14.1 UN-number

Not classified as dangerous goods regarding ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

### 14.2 Proper shipping name

Not applicable.

### 14.3 Class

Not applicable.

### 14.4 Packing group

Not applicable.

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- 14.5 Environmentally hazardous**  
None.
- 14.6 Special precautions for user**  
None.
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code**  
Not applicable. The product is only delivered and transported in packaging approved for traffic purposes.

### Section 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- EC legislation**  
Directive 2012/18/EU  
Employment restrictions: Does not apply.  
Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
- National legislation**  
Water hazard class (D): 0 – non-hazardous to water (AwSV)
- 15.2 Chemical safety assessment**  
For this product, a chemical safety assessment was not carried out.

### Section 16: Other information

Full text of H-Statements referred to under sections 3.2:

H301	Toxic if swallowed.
H330	Fatal if inhaled.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

List of abbreviations:

°C	degree Celsius
ABEK	Gases and vapours of organic compounds with boiling point > 65°C (A), inorganic gases and vapours, e.g. chlorine, hydrogen sulphide, hydrogen cyanide (B), sulphur dioxide, hydrogen chloride (E), ammonia and organic ammonia derivatives (K)
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord européen relatif au transport international des marchandises dangereuses par route)
AwSV	Ordinance on Installations for the Handling of Substances Hazardous to Water
CO	Carbon monoxide
CO <sub>2</sub>	Carbon dioxide
EG/EU	European Union
EN	European Standard
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M

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IMDG	International Maritime Code for Dangerous Goods
IVD	In-vitro-diagnostic
MARPOL	International Convention for the Prevention of Marine Pollution
NIOSH	National Institute for Occupational Safety and Health
PBT	Persistent (P), bioaccumulative (B), toxic (T)
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)
SCL	Specific concentration limit
UN	United Nations
US	United States
vPvB	Very persistent (vP), very bioaccumulative (vB)

### Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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### Changes to the prior version:

Section 2.1	Hazard class and category added
Section 3.2	Hazard class and category added; specific concentration limits and M-factors according legal classification added; annotation adapted
Section 8.2.2.2	Regulation and formulation adapted
Section 11.1	Skin sensitization actualized
Section 15	Regulation adapted
Section 16	Hazard statements according to legal classification adapted; list of abbreviations added