

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

AESKULISA® Autoimmunity

Product identifier

Product name:

AESKULISA® Autoimmunity

Product number:

3xxx*

Article Name	Symbol	MSDS Version	Appendix
Break apart microtiter test strips	MP	010	(1)
Calibrator A – F	CAL	010	(2)
Cut-off Calibrator	CO-CAL	010	(2)
Positive Control	CON +	010	(2)
Negative Control	CON –	010	(2)
Sample Buffer, 5x conc.	SB 5x	010	(3)
Wash Buffer, 50x conc.	WASHB 50x	010	(4)
Anti-Human IgA, IgG or IgM Conjugate	CONJ	010	(5)
Substrate	SUB	011	(6)
Stop Solution	STOP	010	(7)
Recovery**	RC	010	(8)

* except Ref 3602-3606, 3810, 3901-3903

** only in Ref 3402

Appendix 1-8

Safety Data Sheets for single components

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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/undertaking
1.1 Product identifier

Product name:

AESKULISA® Break apart microtiter test strips

Symbol:

MP
1.2 Relevante identifizierte Verwendungen des Stoffs oder Gemischs und Verwendungen, von denen abgeraten wird

This enzyme immunoassay (in-vitro diagnostic or component) is not intend to be other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

AESKU.DIAGNOSTICS GmbH und Co. KG

Mikro-Forum-Ring 2

55234 Wendelsheim

Deutschland

Tel. +49 (0) 6734 – 9622 – 0

Fax +49 (0) 6734 – 9622 – 2222

E-Mail info@aesku.com

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1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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

3.1 Substance

Not applicable.

3.2 Mixture

Not applicable.

Abschnitt 4: Erste-Hilfe-Maßnahmen

4.1 Beschreibung der Erste-Hilfe-Maßnahmen

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.

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. 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.

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. 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

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Disposal: see section 13

Section 7: Handling and storage

7.1 Precautions for safe handling**7.1.1 Advice on safe handling**

Notice the use instructions on the label. 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.

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 programme.

8.2.2.1 Eye/Face protection

Not required.

8.2.2.2 Skin protection/Hand protection

Suitable material: nitrile caoutchouc (nitrile rubber) or butyl caoutchouc (butyl rubber).

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC 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.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form

solid

Colour

colourless

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Odour	odourless
Odour Treshold	Not applicable.
pH	Not applicable.
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	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.

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

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

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Not applicable.

Germ cell mutagenicity

Not applicable.

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.

Section 12: Ecological information

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.

Section 13: Disposal considerations

13.1 Waste treatment methods

Residual product should be disposed in accordance to 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 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.

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- 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
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

Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterizes 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: General revision

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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/undertaking

1.1 Product identifier

Product name:

AESKULISA® Calibrators A – F
AESKULISA® Cut-off Calibrator
AESKULISA® Positive Control
AESKULISA® 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 intend to be other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

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1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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: May cause an allergic skin reaction – 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.


Section 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

Relevant ingredients:

REACH registration number	EC-No.	CAS-No.	Name	Amount % (w/w)	Symbol	H-statements
01-2120764691-48-xxxx	911-418-6	55965-84-9	Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	≤ 0,05	 Signal word: Danger	H301, H331, H311, H314, H317, H400, H410

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

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Not combustible. Danger of formation of toxic pyrolysis products. In case of fire can be released: Carbon monoxide (CO), carbon dioxide (CO₂)

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

Notice the use instructions on the label. 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

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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

Suitable material: nitrile caoutchouc (nitrile rubber) or butyl caoutchouc (butyl rubber)
 The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC 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.
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.

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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:

Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1) ($\leq 0.05\%$)

Classification of the substance: Category 1

SCL: Category 1 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.

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.

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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. 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 in accordance to 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 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.

14.5 Environmentally hazardous

None.

14.6 Special precautions for user

None.

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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**

Control of major-accident hazards involving dangerous substances 96/82/EC

Employment restrictions:

Observe restrictions to employment for juvenils 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.
H331	Toxic if inhaled.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

Further information

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

AESKU.DIAGNOSTICS and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

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Changes to the prior version: General revision, new classification of the mixture

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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/undertaking

1.1 Product identifier

Product name:

AESKULISA® 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 other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

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E-Mail info@aesku.com

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1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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 measureNot combustible. Danger of formation of toxic pyrolysis products. In case of fire can be released: Carbon monoxide (CO), carbon dioxide (CO₂)**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

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Notice the use instructions on the label. 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 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

Suitable material: nitrile caoutchouc (nitrile rubber) or butyl caoutchouc (butyl rubber)

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC 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

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Section 13: Disposal considerations

13.1 Waste treatment methods

Residual product should be disposed in accordance to 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 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.

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**

Control of major-accident hazards involving dangerous substances 96/82/EC

Employment restrictions:

Observe restrictions to employment for juvenils 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

Further information

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

AESKU.DIAGNOSTICS and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

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Changes to the prior version: General revision

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Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Appendix 4 – Safety Data Sheet

Wash Buffer, 50x conc.
WASHB 50x

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

1.1 Product identifier

Product name:

AESKULISA® Wash Buffer, 50x conc.

Symbol:

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 intend to be other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

AESKU.DIAGNOSTICS GmbH und Co. KG

Mikro-Forum-Ring 2

55234 Wendelsheim

Deutschland

Tel. +49 (0) 6734 – 9622 – 0

Fax +49 (0) 6734 – 9622 – 2222

E-Mail info@aesku.com

www.aesku.com

1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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: May cause an allergic skin reaction – 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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Relevant ingredients:

REACH registration number	EC-No.	CAS-No.	Name	Amount % (w/w)	Symbol	H-statements
01-2120764691-48-xxxx	911-418-6	55965-84-9	Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	≤ 0,05	 Signal word: Danger	H301, H331, H311, H314, H317, H400, H410

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. In case of fire can be released: Carbon monoxide (CO), carbon dioxide (CO₂)

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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Notice the use instructions on the label. 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 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

Suitable material: nitrile caoutchouc (nitrile rubber) or butyl caoutchouc (butyl rubber)

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC 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.

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

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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 sensitizationRelevant ingredients:Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1) ($\leq 0.05\%$)

Classification of the substance: Category 1

SCL: Category 1 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.

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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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 in accordance to 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 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.
- 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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Section 15: Regulatory information

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

Control of major-accident hazards involving dangerous substances 96/82/EC

Employment restrictions:

Observe restrictions to employment for juvenils 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.
H331	Toxic if inhaled.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

Further information

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

AESKU.DIAGNOSTICS and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

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Changes to the prior version: General revision, new classification of the mixture

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Appendix 5 – Safety Data Sheet

Anti-Human IgA, IgG or IgM Conjugate
CONJ
Section 1: Identification of the substance/mixture and of the company/undertaking
1.1 Product identifier

Product name:

AESKULISA® Anti-Human IgA, IgG or IgM Conjugate

Symbol:

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 intend to be other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

AESKU.DIAGNOSTICS GmbH und Co. KG

Mikro-Forum-Ring 2

55234 Wendelsheim

Deutschland

Tel. +49 (0) 6734 – 9622 – 0

Fax +49 (0) 6734 – 9622 – 2222

E-Mail info@aesku.com

www.aesku.com

1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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: May cause an allergic skin reaction – 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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Relevant ingredients:

REACH registration number	EC-No.	CAS-No.	Name	Amount % (w/w)	Symbol	H-statements
01-2120764691-48-xxxx	911-418-6	55965-84-9	Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	≤ 0,05	 Signal word: Danger	H301, H331, H311, H314, H317, H400, H410

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. In case of fire can be released: Carbon monoxide (CO), carbon dioxide (CO₂)

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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Notice the use instructions on the label. 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 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

Suitable material: nitrile caoutchouc (nitrile rubber) or butyl caoutchouc (butyl rubber)

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC 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	blue (IgA, IgG, IgA/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.

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

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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 sensitizationRelevant ingredients:Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1) ($\leq 0.05\%$)

Classification of the substance: Category 1

SCL: Category 1 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.

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. 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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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 in accordance to 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 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.
- 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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Section 15: Regulatory information

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

Control of major-accident hazards involving dangerous substances 96/82/EC

Employment restrictions:

Observe restrictions to employment for juvenils 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.
H331	Toxic if inhaled.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterizes 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: General revision, new classification of the mixture

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Appendix 6 – Safety Data Sheet

Substrate
SUB

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

1.1 Product identifier

Product name:

AESKULISA® TMB ELISA Substrat

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 other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

AESKU.DIAGNOSTICS GmbH und Co. KG

Mikro-Forum-Ring 2

55234 Wendelsheim

Deutschland

Tel. +49 (0) 6734 – 9622 – 0

Fax +49 (0) 6734 – 9622 – 2222

E-Mail info@aesku.com

www.aesku.com

1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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. In case of fire can be released: Carbon monoxide (CO), carbon dioxide (CO₂)

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

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

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Wipe up and place in appropriate containers for disposal.

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

Notice the use instructions on the label. 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

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Not required if the product is used as intended.

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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

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- 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 in accordance to 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 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.
- 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**
Control of major-accident hazards involving dangerous substances 96/82/EC
Employment restrictions: Observe restrictions to employment for juvenils 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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Section 16: Other information

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

None

Further information

The information contained herein is based on the present state of our knowledge and should be used as a guide. It characterizes 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: General revision, substitution of a dangerous good

فندیباز

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

Appendix 7 – Safety Data Sheet

Stop Solution
STOP

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

1.1 Product identifier

Product name:

AESKULISA® Stop Solution

Symbol:

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 intend to be other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

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Deutschland

Tel. +49 (0) 6734 – 9622 – 0

Fax +49 (0) 6734 – 9622 – 2222

E-Mail info@aesku.com

www.aesku.com

1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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: May be corrosive to metals – 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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

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Section 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

Relevant ingredients:

REACH registration number	EC-No.	CAS-No.	Name	Amount % (w/w)	Symbol	H-statements
01-2119484862-27-xxxx	231-595-7	7647-01-0	Hydrochloric acid, conc.	< 3.0		H290, H314, H318, H335
Signal word: Danger						

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. In case of fire can be released: Carbon monoxide (CO), carbon dioxide (CO₂)

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.

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

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

Notice the use instructions on the label. 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 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

Suitable material: nitrile caoutchouc (nitrile rubber) or butyl caoutchouc (butyl rubber)

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 12.06.2020

Version: 003

replaced Version: 08.02.2019

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC 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 ³ 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).

10.5 Incompatible materials

Different metals and metal alloys.

10.6 Hazardous decomposition products

Safety Data Sheet

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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/irritationRelevant ingredients:

Hydrochloric acid, conc. (<3,0%) not summated

Classification of the substance: Category 1B

SCL: Category 1B: 25%, Category 1C: 25 %, Category 2: 10%.

The mixture is not classified in acute corrosion/irritation.

Serious eye damage/irritationRelevant ingredients:

Hydrochloric acid, conc. (<3,0%) not summated

Classification of the substance: Category 1B

SCL: Category 1B: 25%, Category 1C: 25 %, Category 2: 10%.

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.

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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 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.
- 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.

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Section 15: Regulatory information

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

Control of major-accident hazards involving dangerous substances 96/82/EC

Employment restrictions:

Observe restrictions to employment for juvenils 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.

Further information

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

AESKU.DIAGNOSTICS and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

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Changes to the prior version: General revision

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Appendix 8 – Safety Data Sheet

Recovery

RC

Section 1: Identification of the substance/mixture and of the company/undertaking
1.1 Product identifier

Product name:

AESKULISA® Recovery

Symbol:

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 intend to be other than for the detection and semi quantitative determination of human IgA/G/M antibodies in autoimmune diagnostics. This in vitro diagnostic is not for samples other than 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

AESKU.DIAGNOSTICS GmbH und Co. KG

Mikro-Forum-Ring 2

55234 Wendelsheim

Deutschland

Tel. +49 (0) 6734 – 9622 – 0

Fax +49 (0) 6734 – 9622 – 2222

E-Mail info@aesku.com

www.aesku.com

1.4 Emergency telephone number

Manufacturer: +49 (0) 6734 – 9622 – 0 (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: May cause an allergic skin reaction – 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

Relevant ingredients:

REACH registration number	EC-No.	CAS-No.	Name	Amount % (w/w)	Symbol	H-statements
01-2120764691-48-xxxx	911-418-6	55965-84-9	Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	≤ 0,05	 Signal word: Danger	H301, H331, H311, H314, H317, H400, H410

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. In case of fire can be released: Carbon monoxide (CO), carbon dioxide (CO₂)

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.

Section 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Notice the use instructions on the label. 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 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

Suitable material: nitrile caoutchouc (nitrile rubber) or butyl caoutchouc (butyl rubber)

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The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC 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.

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

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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 sensitizationRelevant ingredients:Reaction mass of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1) ($\leq 0.05\%$)

Classification of the substance: Category 1

SCL: Category 1 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.

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. 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.

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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 in accordance to 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 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.
- 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.

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Section 15: Regulatory information

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

Control of major-accident hazards involving dangerous substances 96/82/EC

Employment restrictions:

Observe restrictions to employment for juvenils 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.
H331	Toxic if inhaled.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects

Further information

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

AESKU.DIAGNOSTICS and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

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Changes to the prior version: General revision, new classification of the mixture