

Safety Data Sheet

in accordance with Regulation (EC) No 1907/2006

Revision date: 20/10/2025

Version: 002

replaces version of 05/06/2024

AESKUBLOTS® Gluten Related Disorders

Product Identifier

Product name:

AESKUBLOTS® Gluten Related Disorders

Product number:

Gluten Related Disorders IgA

401005

Gluten Related Disorders IgG

401006

<i>Test Component</i>	<i>Symbol</i>	<i>Appendix</i>
Test strips	STRIP	(1)
Washing buffer 20x	WASH 20x	(2)
Anti-human IgX conjugate	CONJ	(3)
Substrate	SUB	(4)
Blocking Reagent	BLOCK REAG	(5)

Always read the instructions for use before using the test kit. Terms and conditions apply.

The information in this product data sheet is based on the current state of our knowledge. They do not constitute a guarantee of product characteristics and do not establish a contractual legal relationship.

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Changes compared to previous version:

Revision of Annex 4.

Appendix 1 - 5

Safety Data Sheets for Individual Components.

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

1.1. Product identifier

Trade name/designation:

AESKUBLOTS® stripes

Other means of identification:

STRIP

Article No.:

401005 , 401006

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

Use of the substance/mixture:

AESKUBLOTS® Gluten Related Disorders

This test is a membrane based enzyme immunoassay for quantitative detection of IgA or IgG subclass antibodies in human serum or plasma. Antigens are applied as lines on a nitrocellulose membrane at defined positions.

The reagents should not be used for purposes other than the specified determination.

The test-kit is for professional use only in laboratories.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Aesku.Diagnostics GmbH & Co. KG

Mikroforum Ring 2

55234 Wendelsheim

Germany

Telephone: +49 6734 9622-0

Telefax: +49 6734 9622-2222

E-mail: info@aesku.com

Website: www.aesku.com

E-mail (competent person): info@aesku.com

1.4. Emergency telephone number

Aesku.Diagnostics GmbH & Co. KG, +49 6734 9622-0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

2.3. Other hazards

Adverse environmental effects:

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

Other adverse effects:

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

No data available

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air.

Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

Protective equipment:

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

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

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6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Further information on storage conditions:

Recommended storage temperature: 2-8°C

7.3. Specific end use(s)

Recommendation:

Item 1.2 and the instructions for use must be observed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection EN 166

Skin protection:

Tested protective gloves must be worn EN ISO 374 In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: solid

Colour: white

Odour: not determined

Safety relevant basis data

Parameter	Value	① Method ② Remark
pH	No data available	
Melting point	No data available	
Freezing point	No data available	

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Parameter	Value	① Method ② Remark
Initial boiling point and boiling range	No data available	
Flash point	not applicable	
Evaporation rate	No data available	
Auto-ignition temperature	not applicable	
Upper/lower flammability or explosive limits	No data available	
Vapour pressure	No data available	
Vapour density	No data available	
Density	No data available	
Bulk density	not applicable	
Water solubility	No data available	
Dynamic viscosity	No data available	
Kinematic viscosity	No data available	

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn. not relevant

10.2. Chemical stability

Recommended storage temperature: 2-8°C

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

SECTION 11: Toxicological information

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

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

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Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

No data available

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
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Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

13.2. Additional information

Do not allow run-off from fire-fighting to enter drains or water courses.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.

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Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

16.2. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, toxic for Reproduction
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC ₅₀	Effective Concentration 50%
ECHA	European Chemicals Agency
EN	European Standard
ENCS	Japanese Inventory of Existing and New Chemical Substances
EWC	European Waste Catalogue
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IC ₅₀	Inhibition Concentration 50 %
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Standards Organisation
KG	body weight
LC ₅₀	Lethal (fatal) Concentration 50%
LD ₅₀	Lethal (fatal) Dose 50%

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NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety & Health
PBT	persistent and bioaccumulative and toxic
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
SVHC	substances of very high concern
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations
vPvB	Very persistent and very bioaccumulative
ZNS	central nervous system
°C	centigrade
AwSV	Ordinance on systems for handling water-polluting substances
CO	carbon monoxide
CO ₂	carbon dioxide
IgA	Immunoglobuline A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IVD	In-Vitro Diagnostic
MARPOL	International Convention for the Prevention of Pollution from Ships

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

No data available

16.6. Training advice

No data available

16.7. Additional information

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

1.1. Product identifier

Trade name/designation:

AESKUBLOTS® Wash Buffer 20X

Other means of identification:

WASH 20x

Article No.:

401005 , 401006

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

Use of the substance/mixture:

AESKUBLOTS® Gluten Related Disorders

This test is a membrane based enzyme immunoassay for quantitative detection of IgA or IgG subclass antibodies in human serum or plasma. Antigens are applied as lines on a nitrocellulose membrane at defined positions.

The reagents should not be used for purposes other than the specified determination.

The test-kit is for professional use only in laboratories.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Aesku.Diagnostics GmbH & Co. KG

Mikroforum Ring 2

55234 Wendelsheim

Germany

Telephone: +49 6734 9622-0

Telefax: +49 6734 9622-2222

E-mail: info@aesku.com

Website: www.aesku.com

E-mail (competent person): info@aesku.com

1.4. Emergency telephone number

Aesku.Diagnostics GmbH & Co. KG, +49 6734 9622-0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

2.3. Other hazards

No data available

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7]; and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1) The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	0 - ≤ 0.0015 weight-%
	ProClin® 300 Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1B (H314), Skin Sens. 1 (H317)  Danger Acute Toxicity Estimate ATE (oral) 862 mg/kg ATE (dermal) 2,800 mg/kg	0 - ≤ 0.001 weight-%

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air.

Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

Protective equipment:

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

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Further information on storage conditions:

Recommended storage temperature: 2-8°C

7.3. Specific end use(s)

Recommendation:

Item 1.2 and the instructions for use must be observed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection EN 166

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Skin protection:

Tested protective gloves must be worn EN ISO 374. In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration. Suitable material: Breakthrough time: min

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: green

Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	7.4 – 7.8	21 °C	
Melting point	No data available		
Freezing point	No data available		
Initial boiling point and boiling range	No data available		
Flash point	not applicable		
Evaporation rate	No data available		
Auto-ignition temperature	not applicable		
Upper/lower flammability or explosive limits	No data available		
Vapour pressure	No data available		
Vapour density	No data available		
Density	No data available		
Bulk density	not applicable		
Water solubility	No data available		
Dynamic viscosity	No data available		
Kinematic viscosity	No data available		

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn. not relevant

10.2. Chemical stability

Recommended storage temperature: 2-8°C

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

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SECTION 11: Toxicological information

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

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

No data available

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
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Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

15.1.1. EU legislation

No data available

15.1.2. National regulations

 [DE] National regulations

Water hazard class

WGK:

1 - slightly hazardous to water

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

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16.2. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AGW	Threshold Limit Value
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, toxic for Reproduction
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC ₅₀	Effective Concentration 50%
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EN	European Standard
EWC	European Waste Catalogue
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IC ₅₀	Inhibition Concentration 50 %
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Standards Organisation
KG	body weight
LC ₅₀	Lethal (fatal) Concentration 50%
LD ₅₀	Lethal (fatal) Dose 50%
MAK	Maximum concentration in the workplace air (CH)
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety & Health
PBT	persistent and bioaccumulative and toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
SCL	Specific concentration limit
SVHC	substances of very high concern
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations
vPvB	Very persistent and very bioaccumulative
ZNS	central nervous system
°C	centigrade
AwSV	Ordinance on systems for handling water-polluting substances
CO	carbon monoxide
CO ₂	carbon dioxide
IgA	Immunoglobuline A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IVD	In-Vitro Diagnostic
MARPOL	International Convention for the Prevention of Pollution from Ships

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

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16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

Hazard statements	
H302	Harmful if swallowed.
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.

16.6. Training advice
No data available

16.7. Additional information

The information is based on the current state of our knowledge. You shall ours Describe products with regard to safety requirements, but do not represent them Assurance of product properties and do not constitute a contractual legal relationship. Copyright ©: Aesku.Diagnostics GmbH & Co. KG, copies may only be used for internal purposes be made.

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AESKUBLOTS® Anti-human IgX Conjugate

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

1.1. Product identifier

Trade name/designation:

AESKUBLOTS® Anti-human IgX Conjugate

Other means of identification:

CONJ

Article No.:

401005 , 401006

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

Use of the substance/mixture:

AESKUBLOTS® Gluten Related Disorders

This test is a membrane based enzyme immunoassay for quantitative detection of IgA or IgG subclass antibodies in human serum or plasma. Antigens are applied as lines on a nitrocellulose membrane at defined positions.

The reagents should not be used for purposes other than the specified determination.

The test-kit is for professional use only in laboratories.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Aesku.Diagnostics GmbH & Co. KG

Mikroforum Ring 2

55234 Wendelsheim

Germany

Telephone: +49 6734 9622-0

Telefax: +49 6734 9622-2222

E-mail: info@aesku.com

Website: www.aesku.com

E-mail (competent person): info@aesku.com

1.4. Emergency telephone number

Aesku.Diagnostics GmbH & Co. KG, +49 6734 9622-0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard components for labelling:

ProClin ® 300; phenol

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

2.3. Other hazards

No data available

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
	ProClin® 300 Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317) Danger Acute Toxicity Estimate ATE (oral) 862 mg/kg ATE (dermal) 2,800 mg/kg	0 - ≤ 0.1 weight-%
CAS No.: 108-95-2 EC No.: 203-632-7 Index No.: 604-001-00-2	phenol Acute Tox. 3 (H301, H331, H311), Aquatic Chronic 2 (H411), Eye Dam. 1 (H318), Muta. 2 (H341), STOT RE 2 (H373), Skin Corr. 1B (H314) Danger Specific concentration limit (SCL) Skin Corr. 1B; H314: C ≥ 3% Skin Irrit. 2; H315: 1% ≤ C < 3% Eye Dam. 1; H318: C ≥ 3% Eye Irrit. 2; H319: 1% ≤ C < 3% Acute Toxicity Estimate ATE (oral) 317 mg/kg ATE (dermal) 630 mg/kg ATE (inhalation, vapour) 3 mg/L ATE (inhalation, dust/mist) 0.5 mg/L	0 - ≤ 0.0066 weight-%

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air.

Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

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5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

Protective equipment:

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

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Further information on storage conditions:

Recommended storage temperature: 2-8°C

7.3. Specific end use(s)

Recommendation:

Item 1.2 and the instructions for use must be observed.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
IDLH (US) from 1 Jan 1994	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 250 ppm
TRGS 900 (DE) from 1 May 2010	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m ³) ② 4 ppm (16 mg/m ³) ⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11
ES from 1 Jan 2012	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m ³) ② 4 ppm (16 mg/m ³) ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI
IOELV (EU) from 17 Dec 2009	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m ³) ② 4 ppm (16 mg/m ³) ⑤ (may be absorbed through the skin)
OSHA (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 5 ppm (19 mg/m ³) ⑤ (may be absorbed through the skin)
NIOSH (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 5 ppm (19 mg/m ³) ③ 15.6 ppm (60 mg/m ³) ⑤ (may be absorbed through the skin)
ACGIH (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 5 ppm (19 mg/m ³) ⑤ (may be absorbed through the skin)

8.1.2. Biological limit values

Limit value type (country of origin)	Substance name	Limit value	① Parameter ② Test material ③ Time of sampling: ④ Remark
TRGS 903 (DE) from 19 Sept 2013	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g Creatinin	① Phenol ② Urin ③ Expositionsende bzw. Schichtende
VLB (ES) from 1 Jan 2013	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinina	① fenol ② orina ③ fin de exposición o fin de turno
ACGIH-BEI (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	250 mg/g creatinine	① phenol ② urine ③ end of exposure or end of shift
BLV (EU) from 1 Jun 2014	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

8.1.3. DNEL-/PNEC-values

No data available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection EN 166

Skin protection:

Tested protective gloves must be worn EN ISO 374 .In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration. Suitable material: Breakthrough time: min

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: transparent

Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.7 – 6.9	21 °C	
Melting point	No data available		
Freezing point	No data available		
Initial boiling point and boiling range	No data available		
Flash point	not applicable		
Evaporation rate	No data available		
Auto-ignition temperature	not applicable		
Upper/lower flammability or explosive limits	No data available		
Vapour pressure	No data available		
Vapour density	No data available		
Density	No data available		
Bulk density	not applicable		
Water solubility	No data available		
Dynamic viscosity	No data available		
Kinematic viscosity	No data available		

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn. not relevant

10.2. Chemical stability

Storage temperature: 2-8°C

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

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10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

SECTION 11: Toxicological information

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

ProClin ® 300

LD₅₀ oral: 862 mg/kg (Ratte)

LD₅₀ dermal: 2,800 mg/kg (Kaninchen)

phenol CAS No.: 108-95-2 EC No.: 203-632-7

LD₅₀ oral: 317 mg/kg (Ratte)

LD₅₀ dermal: 630 mg/kg (Kaninchen)

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Contains ProClin ® 300. May produce an allergic reaction.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

No data available

11.2. Information on other hazards

No data available

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SECTION 12: Ecological information

12.1. Toxicity

phenol CAS No.: 108-95-2 EC No.: 203-632-7

LC₅₀: 8.9 mg/L 4 d (fish)

EC₅₀: 3.1 mg/L 2 d

LC₅₀: 21.93 mg/L (fish)

EC₅₀: 10 mg/L

NOEC: 0.077 mg/L (fish)

12.2. Persistence and degradability

ProClin ® 300

Biodegradation: Poorly biodegradable.

phenol CAS No.: 108-95-2 EC No.: 203-632-7

Biodegradation: Yes, rapidly

12.3. Bioaccumulative potential

phenol CAS No.: 108-95-2 EC No.: 203-632-7

Log K_{ow}: 1.47

Bioconcentration factor (BCF): 17.5

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

ProClin ® 300

Results of PBT and vPvB assessment: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

phenol CAS No.: 108-95-2 EC No.: 203-632-7

Results of PBT and vPvB assessment: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

13.2. Additional information

Do not allow run-off from fire-fighting to enter drains or water courses.

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SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

15.1.1. EU legislation

No data available

15.1.2. National regulations

 [DE] National regulations

Water hazard class

WGK:

1 - slightly hazardous to water

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

16.2. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC ₅₀	Effective Concentration 50%
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EN	European Standard

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ES	Exposure scenario
EWC	European Waste Catalogue
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IC ₅₀	Inhibition Concentration 50 %
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Standards Organisation
KG	body weight
LC ₅₀	Lethal (fatal) Concentration 50%
LD ₅₀	Lethal (fatal) Dose 50%
MAK	Maximum concentration in the workplace air (CH)
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety & Health
NOEC	No Observed Effect Concentration
OEL	Threshold Limit Value
OSHA	Occupational Safety & Health Administration
PBT	persistent and bioaccumulative and toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
SCL	Specific concentration limit
SVHC	substances of very high concern
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations
ZNS	central nervous system
°C	centigrade
AwSV	Ordinance on systems for handling water-polluting substances
CO	carbon monoxide
CO ₂	carbon dioxide
IgA	Immunoglobuline A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IVD	In-Vitro Diagnostic
MARPOL	International Convention for the Prevention of Pollution from Ships

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

Hazard statements	
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.

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Hazard statements	
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

16.6. Training advice

No data available

16.7. Additional information

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AESKUBLOTS® Substrate

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

1.1. Product identifier

Trade name/designation:

AESKUBLOTS® Substrate

Other means of identification:

SUB

Article No.:

400x, 40100x, 421xxx, 421xxx.BULK.120, 431xxx, 431xxx.BULK120

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

Use of the substance/mixture:

AESKUBLOTS®

Component for in vitro tests for scientific research and development. For professional use only.

1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

Aesku.Diagnostics GmbH & Co. KG

Mikroforum Ring 2

55234 Wendelsheim

Germany

Telephone: +49 6734 9622-0

Telefax: +49 6734 9622-2222

E-mail: info@aesku.com

Website: www.aesku.com

1.4. Emergency telephone number

No data available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

2.3. Other hazards

Adverse physicochemical effects:

No information available.

Adverse human health effects and symptoms:

No information available.

Adverse environmental effects:

No information available.

Other adverse effects:

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

No data available

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AESKUBLOTS® Substrate

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

When in doubt or if symptoms are observed, get medical advice.

Following inhalation:

Provide fresh air.

In case of skin contact:

Wash with plenty of water.

After eye contact:

Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing.

Following ingestion:

Rinse mouth immediately and drink 1 glass of water.

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

No data 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 foam to extinguish.

Unsuitable extinguishing media:

Full water jet

5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

Hazardous combustion products:

CO carbon monoxide

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Personal protection equipment: see section 8

6.1.2. For emergency responders

Personal protection equipment:

Use personal protective equipment as required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Take up mechanically.

For cleaning up:

Wipe up with absorbent material (eg. cloth, fleece).

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8

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AESKUBLOTS® Substrate

6.5. Additional information

No further relevant information available.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Item 1.2 and the instructions for use must be observed.

Fire prevent measures:

No special fire protection measures are necessary.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels:

Keep container tightly closed. Keep cool. Keep/Store only in original container. Never return spills in original containers for re-use.

Hints on storage assembly:

Keep away from: Food and feedingstuffs

Storage class (TRGS 510, Germany): 12 – non-combustible liquids that cannot be assigned to any of the above storage classes

Further information on storage conditions:

Recommended storage temperature: 2-8°C

7.3. Specific end use(s)

Recommendation:

Item 1.2 and the instructions for use must be observed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye protection: not required.

Skin protection:

Hand protection: When handling chemical working substances, only chemical protective gloves with a CE mark including a four-digit test number may be worn. Chemical protective gloves must be selected according to the specific workplace, depending on the concentration and quantity of the hazardous substance. It is recommended to clarify the chemical resistance of the above-mentioned protective gloves for specific applications with the glove manufacturer.

Suitable material: NBR (nitrile rubber)

Glove material thickness: ≥ 0.1 mm

Breakthrough time: > 480 min

Take recovery breaks to allow the skin to regenerate.

Body protection: Use of protective clothing

Respiratory protection:

Usually no personal respiratory protection necessary.

Thermal hazards:

No special handling advices are necessary.

8.2.3. Environmental exposure controls

No special environmental measures are necessary.

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8.3. Additional information

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: not determined

Odour: odourless

flammability: No

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	4.7 – 5.3	21 °C	
Melting point	No data available		
Freezing point	No data available		
Initial boiling point and boiling range	100 °C		
Flash point	380 °C		
Evaporation rate	No data available		
Auto-ignition temperature	not applicable		
Upper/lower flammability or explosive limits	No data available		
Vapour pressure	No data available		
Vapour density	No data available		
Density	1.007 g/cm ³		
Bulk density	not applicable		
Water solubility	No data available		
Dynamic viscosity	No data available		
Kinematic viscosity	No data available		

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

10.5. Incompatible materials

metals (including their alloys)

10.6. Hazardous decomposition products

No known hazardous decomposition products.

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SECTION 11: Toxicological information

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

Toxicological information

Acute Toxicity Estimate for Mixtures

ATE (oral): >2,000 mg/kg

ATE (dermal): >2,000 mg/kg

ATE (inhalation, vapour): >20 mg/L

ATE (inhalation, dust/mist): >5 mg/L

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

Relevante Bestandteile

Results of PBT and vPvB assessment: —

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

16 05 09	(16) WASTES NOT OTHERWISE SPECIFIED IN THE LIST (05) gases in pressure containers and discarded chemicals (09) discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08
----------	---

Waste code packaging

15 01 02	(15) WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED (01) packaging (including separately collected municipal packaging waste) (02) Plastic packaging
----------	--

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.

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Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

16.2. Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Classification, Labelling and Packaging
EWC	European Waste Catalogue
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
KG	body weight
NFPA	National Fire Protection Association
PBT	persistent and bioaccumulative and toxic
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

No data available

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16.6. Training advice

No data available

16.7. Additional information

No data available

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

1.1. Product identifier

Trade name/designation:

AESKUBLOTS® Blocking Reagent

Other means of identification:

BLOCK-REAG

Article No.:

401005 , 401006

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

Use of the substance/mixture:

AESKUBLOTS® Gluten Related Disorders

This test is a membrane based enzyme immunoassay for quantitative detection of IgA or IgG subclass antibodies in human serum or plasma. Antigens are applied as lines on a nitrocellulose membrane at defined positions.

The reagents should not be used for purposes other than the specified determination.

The test-kit is for professional use only in laboratories.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Aesku.Diagnostics GmbH & Co. KG

Mikroforum Ring 2

55234 Wendelsheim

Germany

Telephone: +49 6734 9622-0

Telefax: +49 6734 9622-2222

E-mail: info@aesku.com

Website: www.aesku.com

E-mail (competent person): info@aesku.com

1.4. Emergency telephone number

Aesku.Diagnostics GmbH & Co. KG, +49 6734 9622-0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

2.3. Other hazards

Adverse environmental effects:

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

Other adverse effects:

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

No data available

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air.

Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

Protective equipment:

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

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

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6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Further information on storage conditions:

Recommended storage temperature: 2-8°C

7.3. Specific end use(s)

Recommendation:

Item 1.2 and the instructions for use must be observed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection EN 166

Skin protection:

Tested protective gloves must be worn EN ISO 374 In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: solid

Colour: white

Odour: not determined

Safety relevant basis data

Parameter	Value	① Method ② Remark
pH	No data available	
Melting point	No data available	
Freezing point	No data available	

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Parameter	Value	① Method ② Remark
Initial boiling point and boiling range	No data available	
Flash point	not applicable	
Evaporation rate	No data available	
Auto-ignition temperature	not applicable	
Upper/lower flammability or explosive limits	No data available	
Vapour pressure	No data available	
Vapour density	No data available	
Density	No data available	
Bulk density	not applicable	
Water solubility	No data available	
Dynamic viscosity	No data available	
Kinematic viscosity	No data available	

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn. not relevant

10.2. Chemical stability

Recommended storage temperature: 2-8°C

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

SECTION 11: Toxicological information

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

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

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Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

No data available

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

13.2. Additional information

Do not allow run-off from fire-fighting to enter drains or water courses.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.

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14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

16.2. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AGW	Threshold Limit Value
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, toxic for Reproduction
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC ₅₀	Effective Concentration 50%
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EN	European Standard
EWC	European Waste Catalogue
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
IC ₅₀	Inhibition Concentration 50 %
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Standards Organisation
KG	body weight
LC ₅₀	Lethal (fatal) Concentration 50%

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LD ₅₀	Lethal (fatal) Dose 50%
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety & Health
PBT	persistent and bioaccumulative and toxic
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
SVHC	substances of very high concern
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations
vPvB	Very persistent and very bioaccumulative
ZNS	central nervous system
°C	centigrade
AwSV	Ordinance on systems for handling water-polluting substances
CO	carbon monoxide
CO ₂	carbon dioxide
IgA	Immunoglobuline A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IVD	In-Vitro Diagnostic
MARPOL	International Convention for the Prevention of Pollution from Ships

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

No data available

16.6. Training advice

No data available

16.7. Additional information

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