Safety Data Sheet
According to Regulation (EG) Nr. 1907/2006
Revision Date: 29.11.2022 Version: 004 replaced Version: 10.11.2020

AESKULISA® Diabetes Panel

Product identifier
Product name: ***AESKULISA®* Diabetes Panel**
Product number: **3602, 3603, 3604, 3605, 3606**

Article Name	*Symbol*	*Appendix*
Break apart microtiter test strips	MP	(1)
Calibrator A – F	CAL	(2)
Cut-off Calibrator	CO-CAL	(2)
Positive Control	CON +	(2)
Negative Control	CON –	(2)
Sample Buffer, 5x conc.	SB 5x	(3)
Wash Buffer, 50x conc.	WASHB 50x	(4)
Anti-Human IgG Conjugate	CONJ	(5)
Substrate	SUB	(6)
Stop Solution	STOP	(7)
Reconstitution Buffer	RB	(8)
IA2-Biotin*	IA2-Biotin	(9)
GAD65-Biotin**	GAD65-Biotin	(9)
IA2-GAD65-Biotin***	IA2-GAD65-Biotin	(9)

* only in Ref 3602 and 3605

** only in Ref 3603 and 3606

*** only in Ref 3604

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

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Changes to the prior version:

Commission Regulation (EU) 2020/878 of June 18, 2020, amends Annex II to Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH).

Appendix 1-9
Safety Data Sheets for single components

AESKULISA® Break apart microtiter test strips

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

1.1. Product identifier

Trade name/designation:

AESKULISA® Break apart microtiter test strips

Other means of identification:

MP

Article No.:

3xxx

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

Use of the substance/mixture:

AESKULISA®
This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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].

Additional information:

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

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

Special rules for supplemental label elements for certain mixtures:

1,6 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).
2,9 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

2.3. Other hazards

Adverse physicochemical effects:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

AESKULISA® Break apart microtiter test strips

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).

AESKULISA® Break apart microtiter test strips

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:
Lagerung bei +2°C bis +8°C.

7.3. Specific end use(s)
No data available

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 Suitable material: Breakthrough time: min 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: whitish
Odour: not determined

9.2. Other information
No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
The product itself does not burn. not relevant

AESKULISA® Break apart microtiter test strips

10.2. Chemical stability
Recommended storage temperature: 2-8°C

10.3. Possibility of hazardous reactions
No. Product becomes unusable.

10.4. Conditions to avoid
Licht, Hitze, Feuchtigkeit (Es folgt keine gefährliche Reaktion, das Produkt wird unbrauchbar).

10.5. Incompatible materials
No data available

10.6. Hazardous decomposition products
In case of fire: Gases/vapours, toxic

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

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.

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
No data available

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

16.1. Indication of changes
Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

AESKULISA® Break apart microtiter test strips

16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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. Relevant R-, H- and EUH-phrases (Number and full text)

No data available

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.

AESKULISA ® Calibrators A-F (CAL) AESKULISA ® Cut-off Calibrator (CO-CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

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

1.1. Product identifier

Trade name/designation:

AESKULISA ® Calibrators A-F (CAL) AESKULISA ® Cut-off Calibrator (CO-CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

Article No.:
3xxx

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

Use of the substance/mixture:

AESKULISA®
This enzyme immunoassay (in vitro diagnostic tool or component) is not intended for anything other than the detection and semi-quantitative determination of human IgA / IgG / IgM antibodies against specific antigens in autoimmune diagnostics.This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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

Special rules for supplemental label elements for certain mixtures:

1,5 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).
3,2 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

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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.

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**	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%	0 – < 0.007 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.

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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).

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
WEL (GB)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (7.8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11
ES	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI
IOELV (EU)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (may be absorbed through the skin)
VRC (FR)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (7.8 mg/m³) ② 4 ppm (15.6 mg/m³) ⑤ (peut être absorbé par la peau)
GR	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (αναμένετε απορρόφηση από το δέρμα)
ACGIH (US)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 5 ppm (19 mg/m³) 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)	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)	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)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

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8.1.3. DNEL-/PNEC-values
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 Suitable material: Breakthrough time: min 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: Liquid
Colour: yellow-orange
Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.7 – 6.9	21 °C	
Melting point	*not determined*		
Freezing point	*not determined*		
Initial boiling point and boiling range	*not determined*		
Decomposition temperature	*not determined*		
Flash point	*not determined*		
Evaporation rate	*not determined*		
Auto-ignition temperature	*not determined*		
Upper/lower flammability or explosive limits	*not determined*		
Vapour pressure	*not determined*		
Vapour density	*not determined*		
Density	*not determined*		
Relative density	*not determined*		
Bulk density	*not determined*		
Water solubility	*not determined*		
Partition coefficient: n-octanol/water	*not determined*		
Dynamic viscosity	*not determined*		
Kinematic viscosity	*not determined*		

9.2. Other information
No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
The product itself does not burn. not relevant

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

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
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

phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7
LD_{50} oral: 317 mg/kg (Ratte)
LD_{50} 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:
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
Endocrine disrupting properties:
This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

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SECTION 12: Ecological information

12.1. Toxicity

phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7
LC_{50}: 8.9 mg/L 4 d (fish)
EC_{50}: 3.1 mg/L 2 d
LC_{50}: 21.93 mg/L (fish)
EC_{50}: 10 mg/L
NOEC: 0.077 mg/L (fish)

12.2. Persistence and degradability

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

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.

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.

AESKULISA ® Calibrators A-F (CAL) AESKULISA ® Cut-off Calibrator (CO-CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
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 - schwach wassergefährdend

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

16.1. Indication of changes
Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms
°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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. Relevant R-, H- and EUH-phrases (Number and full text)

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.
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

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.

AESKULISA ® Sample Dilution Buffer 5x

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

1.1. Product identifier

Trade name/designation:

AESKULISA ® Sample Dilution Buffer 5x

Other means of identification:

SB 5x

Article No.:

3xxx

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

Use of the substance/mixture:

AESKULISA®
This enzyme immunoassay (in vitro diagnostic tool or component) is not intended for anything other than the detection and semi-quantitative determination of human IgA / IgG / IgM antibodies against specific antigens in autoimmune diagnostics.This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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 human health effects and symptoms:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

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

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.: 26628-22-8 **EC No.:** 247-852-1 **REACH No.:** 01-2119457019-37	**Natriumazid** Acute Tox. 1 (H310), Acute Tox. 2 (H300, H330), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), STOT RE 2 (H373) **Danger**	0.01 – ≤ 0.05 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.

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

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
WEL (GB)	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	① 0.1 mg/m³ ② 0.3 mg/m³ ⑤ (may be absorbed through the skin)
ES	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	① 0.1 mg/m³ ② 0.3 mg/m³ ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLI
VRC (FR)	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	① 0.1 mg/m³ ② 0.3 mg/m³ ⑤ (peut être absorbé par la peau)

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
ACGIH (US)	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	③ 0.29 mg/m³ ⑤ (as Sodium azide)
GR	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	① 0.1 ppm (0.3 mg/m³) ② 0.1 ppm (0.3 mg/m³)
ACGIH (US)	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	③ 0.11 ppm ⑤ (as Hydrazoic acid vapour)
IOELV (EU)	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	① 0.1 mg/m³ ② 0.3 mg/m³ ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1	① 0.2 mg/m³ ② 0.4 mg/m³ ⑤ (einatembare Fraktion) DFG, EU

8.1.2. Biological limit values
No data available

8.1.3. DNEL-/PNEC-values
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 Suitable material: Breakthrough time: min 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: Liquid
Colour: yellow
Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	7.4 – 7.6	21 °C	
Melting point	*not determined*		
Freezing point	*not determined*		
Initial boiling point and boiling range	*not determined*		
Decomposition temperature	*not determined*		
Flash point	*not determined*		

Parameter	Value	at °C	① Method ② Remark
Evaporation rate	*not determined*		
Auto-ignition temperature	*not determined*		
Upper/lower flammability or explosive limits	*not determined*		
Vapour pressure	*not determined*		
Vapour density	*not determined*		
Density	*not determined*		
Relative density	*not determined*		
Bulk density	*not determined*		
Water solubility	*not determined*		
Partition coefficient: n-octanol/water	*not determined*		
Dynamic viscosity	*not determined*		
Kinematic viscosity	*not determined*		

9.2. Other information
No data available

SECTION 10: Stability and reactivity

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

10.2. Chemical stability
No data available

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

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

Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1
LD_{50} oral: 27 mg/kg (Rat) TOXNET
LD_{50} dermal: 20 mg/kg (Rat) TOXNET

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

Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1
LC_{50}: 2.75 mg/L 4 d (fish) ECHA
EC_{50}: 0.35 mg/L 4 d (Algae/water plant) ECHA

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

Natriumazid **CAS No.:** 26628-22-8 **EC No.:** 247-852-1
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 to enter into surface water or drains.

AESKULISA ® Sample Dilution Buffer 5x

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:
nwg - nicht wassergefährdend

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

16.1. Indication of changes
Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms
°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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.

AESKULISA® wash buffer, 50x conc.

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

1.1. Product identifier

Trade name/designation:

AESKULISA® wash buffer, 50x conc.

Other means of identification:

WASHB 50x

Article No.:

3xxx

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

Use of the substance/mixture:

AESKULISA®
This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment *(Aquatic Chronic 3)*	H412: Harmful to aquatic life with long lasting effects.	

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 for environmental hazards	
H412	Harmful to aquatic life with long lasting effects.

Supplemental hazard information	
EUH208	Contains ProClin ® 300. May produce an allergic reaction.

Precautionary statements Prevention	
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.

Precautionary statements Disposal	
P501	Dispose of contents/container to ....

2.3. Other hazards

Adverse human health effects and symptoms:
This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

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.

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. 1B (H314), Skin Sens. 1 (H317) **Danger**	0.1 – ≤ 0.5 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 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:
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.

AESKULISA® wash buffer, 50x conc.

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.

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

AESKULISA® wash buffer, 50x conc.

Skin protection:
Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min 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: 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	*not determined*		
Freezing point	*not determined*		
Initial boiling point and boiling range	*not determined*		
Decomposition temperature	*not determined*		
Flash point	*not determined*		
Evaporation rate	*not determined*		
Auto-ignition temperature	*not determined*		
Upper/lower flammability or explosive limits	*not determined*		
Vapour pressure	*not determined*		
Vapour density	*not determined*		
Density	*not determined*		
Relative density	*not determined*		
Bulk density	*not determined*		
Water solubility	*not determined*		
Partition coefficient: n-octanol/water	*not determined*		
Dynamic viscosity	*not determined*		
Kinematic viscosity	*not determined*		

9.2. Other information
No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
The product itself does not burn.

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

10.3. Possibility of hazardous reactions
Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

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

AESKULISA® wash buffer, 50x conc.

SECTION 11: Toxicological information

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

ProClin ® 300
LD_{50} oral: 862 mg/kg (Ratte)
LD_{50} dermal: 2,800 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

SECTION 12: Ecological information

12.1. Toxicity
Aquatic toxicity:
Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

ProClin ® 300
Biodegradation: Yes, slowly

12.3. Bioaccumulative potential
No data available

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.

AESKULISA® wash buffer, 50x conc.

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.

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:
2 - deutlich wassergefährdend

15.2. Chemical Safety Assessment
No data available

AESKULISA® wash buffer, 50x conc.

SECTION 16: Other information

16.1. Indication of changes

Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment *(Aquatic Chronic 3)*	H412: Harmful to aquatic life with long lasting effects.	

16.5. Relevant R-, H- and EUH-phrases (Number and full text)

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.

AESKULISA ® anti human IgG conjugate

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

1.1. Product identifier

Trade name/designation:

AESKULISA ® anti human IgG conjugate

Article No.:
3xxx

UFI:
NQ2Q-4HTP-WKGD-RXYV

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

Use of the substance/mixture:
AESKULISA
This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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].

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

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	
EUH208	Contains ProClin ® 300. May produce an allergic reaction.

Precautionary statements: none

Special rules for supplemental label elements for certain mixtures:
1,5 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).
2,8 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

AESKULISA ® anti human IgG conjugate

2.3. Other hazards

Adverse human health effects and symptoms:
This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Adverse environmental effects:
The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

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**	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%	0 – < 0.007 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
WEL (GB)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (7.8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11
ES	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI
IOELV (EU)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (may be absorbed through the skin)
VRC (FR)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (7.8 mg/m³) ② 4 ppm (15.6 mg/m³) ⑤ (peut être absorbé par la peau)
GR	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (αναμένετε απορρόφηση από το δέρμα)
ACGIH (US)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 5 ppm (19 mg/m³) 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)	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)	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)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

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8.1.3. DNEL-/PNEC-values
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 Suitable material: Breakthrough time: min 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: Liquid **Colour:** blue
Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.7 – 6.9	21 °C	
Melting point	*not determined*		
Freezing point	*not determined*		
Initial boiling point and boiling range	*not determined*		
Decomposition temperature	*not determined*		
Flash point	*not determined*		
Evaporation rate	*not determined*		
Auto-ignition temperature	*not determined*		
Upper/lower flammability or explosive limits	*not determined*		
Vapour pressure	*not determined*		
Vapour density	*not determined*		
Density	*not determined*		
Relative density	*not determined*		
Bulk density	*not determined*		
Water solubility	*not determined*		
Partition coefficient: n-octanol/water	*not determined*		
Dynamic viscosity	*not determined*		
Kinematic viscosity	*not determined*		

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
Empfohlenen Lagertemperatur: 2-8°C.

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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

ProClin ® 300
LD_{50} oral: 862 mg/kg (Ratte)
LD_{50} dermal: 2,800 mg/kg (Kaninchen)
phenol CAS No.: 108-95-2 **EC No.:** 203-632-7
LD_{50} oral: 317 mg/kg (Ratte)
LD_{50} 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
LC_{50}: 8.9 mg/L 4 d (fish)
EC_{50}: 3.1 mg/L 2 d
LC_{50}: 21.93 mg/L (fish)
EC_{50}: 10 mg/L
NOEC: 0.077 mg/L (fish)

12.2. Persistence and degradability

ProClin ® 300
Biodegradation: Yes, slowly
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.

AESKULISA ® anti human IgG conjugate

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 - schwach wassergefährdend

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

16.1. Indication of changes
Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms
°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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. Relevant R-, H- and EUH-phrases (Number and full text)

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.
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

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.

AESKULISA® Substrate

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

1.1. Product identifier

Trade name/designation:

AESKULISA® Substrate

Other means of identification:

SUB

Article No.:

3xxx

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

Use of the substance/mixture:

AESKULISA®
This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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

Special rules for supplemental label elements for certain mixtures:

1,6 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).
2,9 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

2.3. Other hazards

Other adverse 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.

AESKULISA® Substrate

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).

AESKULISA® Substrate

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 Suitable material: Breakthrough time: min 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: Liquid
Colour: clear
Odour: not determined

9.2. Other information
No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
The product itself does not burn. not relevant

AESKULISA® Substrate

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

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.
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

AESKULISA® Substrate

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 to enter into surface water or drains.

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

AESKULISA® Substrate

15.1.2. National regulations

[DE] National regulations

Water hazard class

WGK:

nwg - nicht wassergefährdend

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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. Relevant R-, H- and EUH-phrases (Number and full text)

No data available

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.

AESKULISA® Stop

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

1.1. Product identifier

Trade name/designation:

AESKULISA® Stop

Article No.:
3xxx

UFI:
AP97-W9QH-HXND-8YGK

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

Use of the substance/mixture:
AESKULISA®
This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Corrosive to metals *(Met. Corr. 1)*	H290: May be corrosive to metals.	On basis of test data.

2.2. Label elements

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

Hazard pictograms:

GHS05
Corrosion

Signal word: Warning

Hazard statements for physical hazards	
H290	May be corrosive to metals.

AESKULISA® Stop

Supplemental hazard information: none

Precautionary statements Prevention	
P234	Keep only in original packaging.

Precautionary statements Response	
P390	Absorb spillage to prevent material damage.

Special rules for supplemental label elements for certain mixtures:
Reduced labeling (≤125 ml)
Signal word: none
Symbol: none

2.3. Other hazards
No data available

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.: 7647-01-0 **EC No.:** 231-595-7 **Index No.:** 017-002-01-X	**hydrogen chloride** Met. Corr. 1 (H290), STOT SE 3 (H335), Skin Corr. 1B (H314) **Danger** **Specific concentration limit (SCL)** Met. Corr. 1; H290: C ≥ 0.1% Skin Corr. 1B; H314: C ≥ 25% Skin Irrit. 2; H315: 10% ≤ C < 25% Eye Dam. 1; H318: C ≥ 25% Eye Irrit. 2; H319: 10% ≤ C < 25% STOT SE 3; H335: C ≥ 10%	1 – ≤ 3 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. In case of respiratory tract irritation, consult a physician.

In case of skin contact:
After contact with skin, wash immediately with plenty of water and soap.

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

AESKULISA® Stop

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.

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:
Lagerung bei +2°C bis +8°C.

7.3. Specific end use(s)
No data available

AESKULISA® Stop

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
TRGS 900 (DE)	hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7	① 2 ppm (3 mg/m³) ② 4 ppm (6 mg/m³) ⑤ (Chlorwasserstoff) DFG, EU, Y
ES	hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7	① 5 ppm (7.6 mg/m³) ② 10 ppm (15 mg/m³) ⑤ VLI
IOELV (EU)	hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7	① 5 ppm (8 mg/m³) ② 10 ppm (15 mg/m³) ⑤ (Hydrogen chloride)
VRC (FR)	hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7	② 5 ppm (7.6 mg/m³) ⑤ (chlorure d'hydrogéne)
WEL (GB)	hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7	① 1 ppm (2 mg/m³) ② 5 ppm (8 mg/m³) ⑤ (gas and aerosol mists)
GR	hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7	① 5 ppm (7 mg/m³) ② 5 ppm (7 mg/m³) ⑤ (υδροχλώριο)
ACGIH (US)	hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7	③ 2 ppm (2.98 mg/m³) ⑤ (A4)

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

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 Suitable material: Breakthrough time: min 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

AESKULISA® Stop

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid **Colour:** clear

Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	2.6 – 3.2	21 °C	
Melting point	*not determined*		
Freezing point	*not determined*		
Initial boiling point and boiling range	*not applicable*		
Decomposition temperature	*not determined*		
Flash point	*not determined*		
Evaporation rate	*not determined*		
Auto-ignition temperature	*not determined*		
Upper/lower flammability or explosive limits	*not determined*		
Vapour pressure	*not determined*		
Vapour density	*not determined*		
Density	*not determined*		
Relative density	*not determined*		
Bulk density	*not determined*		
Water solubility	*not determined*		
Partition coefficient: n-octanol/water	*not determined*		
Dynamic viscosity	*not determined*		
Kinematic viscosity	*not determined*		

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn. May be corrosive to metals.

10.2. Chemical stability

Empfohlenen Lagertemperatur: 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

SECTION 11: Toxicological information

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

hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7
LC_{50} Acute inhalation toxicity (vapour): >5,010 mg/L (Rabbit)

AESKULISA® Stop

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

hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7
LC_{50}: 250 mg/L 2 d

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

hydrogen chloride **CAS No.:** 7647-01-0 **EC No.:** 231-595-7
Results of PBT and vPvB assessment: —

12.6. Endocrine disrupting properties
No data available

12.7. Other adverse effects
No data available

AESKULISA® Stop

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.

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

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Corrosive to metals *(Met. Corr. 1)*	H290: May be corrosive to metals.	On basis of test data.

16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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.

AESKULISA ® Reconstitution Buffer (RB)

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

1.1. Product identifier

Trade name/designation:

AESKULISA ® Reconstitution Buffer (RB)

Other means of identification:
RB

Article No.:
3602, 3603, 3604, 3605, 3606

UFI:
NQ2Q-4HTP-WKGD-RXYV

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

Use of the substance/mixture:
AESKULISA
This enzyme immunoassay (in vitro diagnostic tool or component) is not intended for anything other than the detection and semi-quantitative determination of human IgA / IgG / IgM antibodies against specific antigens in autoimmune diagnostics.This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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	
EUH208	Contains ProClin ® 300. May produce an allergic reaction.

Precautionary statements: none

2.3. Other hazards

Adverse human health effects and symptoms:
This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Adverse environmental effects:
The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

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

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**	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%	0 – < 0.007 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.

AESKULISA ® Reconstitution Buffer (RB)

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
WEL (GB)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (7.8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11
ES	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI
IOELV (EU)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (may be absorbed through the skin)
VRC (FR)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (7.8 mg/m³) ② 4 ppm (15.6 mg/m³) ⑤ (peut être absorbé par la peau)
GR	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 2 ppm (8 mg/m³) ② 4 ppm (16 mg/m³) ⑤ (αναμένετε απορρόφηση από το δέρμα)
ACGIH (US)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	① 5 ppm (19 mg/m³) 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)	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)	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)	phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

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8.1.3. DNEL-/PNEC-values
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 Suitable material: Breakthrough time: min 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: Liquid **Colour:** red
Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.7 – 6.9	21 °C	
Melting point	*not determined*		
Freezing point	*not determined*		
Initial boiling point and boiling range	*not determined*		
Decomposition temperature	*not determined*		
Flash point	*not determined*		
Evaporation rate	*not determined*		
Auto-ignition temperature	*not determined*		
Upper/lower flammability or explosive limits	*not determined*		
Vapour pressure	*not determined*		
Vapour density	*not determined*		
Density	*not determined*		
Relative density	*not determined*		
Bulk density	*not determined*		
Water solubility	*not determined*		
Partition coefficient: n-octanol/water	*not determined*		
Dynamic viscosity	*not determined*		
Kinematic viscosity	*not determined*		

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 No known hazardous reactions.

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10.3. Possibility of hazardous reactions
Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

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

ProClin ® 300
LD_{50} oral: 862 mg/kg (Ratte)
LD_{50} dermal: 2,800 mg/kg (Kaninchen)
phenol CAS No.: 108-95-2 **EC No.:** 203-632-7
LD_{50} oral: 317 mg/kg (Ratte)
LD_{50} 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

AESKULISA ® Reconstitution Buffer (RB)

SECTION 12: Ecological information

12.1. Toxicity

phenol **CAS No.:** 108-95-2 **EC No.:** 203-632-7
LC_{50}: 8.9 mg/L 4 d (fish)
EC_{50}: 3.1 mg/L 2 d
LC_{50}: 21.93 mg/L (fish)
EC_{50}: 10 mg/L
NOEC: 0.077 mg/L (fish)

12.2. Persistence and degradability

ProClin ® 300
Biodegradation: Yes, slowly
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 to enter into surface water or drains.

AESKULISA ® Reconstitution Buffer (RB)

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 - schwach wassergefährdend

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

16.1. Indication of changes
Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms
°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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. Relevant R-, H- and EUH-phrases (Number and full text)

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.
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

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

1.1. Product identifier

Trade name/designation:

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Other means of identification:

IA2-Biotin
GAD65-Biotin
IA2-GAD65-Biotin

Article No.:

3602,3603,3604,3605,3606

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

Use of the substance/mixture:

AESKULISA®
This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.Diagnostics
Mikroforumring 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, +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 human health effects and symptoms:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

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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.

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.

After eye contact:
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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.

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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:
Collect spillage. Measures to prevent aerosol and dust generation Wet clean or vacuum up solids.

For cleaning up:
Water (with cleaning agent)

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).

Measures to prevent aerosol and dust generation:
Dust should be exhausted directly at the point of origin.

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 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:
Particle filter device (EN 143)

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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:** whitish
Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.4 – 6.8	21 °C	
Melting point	*not determined*		
Freezing point	*not determined*		
Initial boiling point and boiling range	*not determined*		
Decomposition temperature	*not determined*		
Flash point	*not determined*		
Evaporation rate	*not determined*		
Auto-ignition temperature	*not determined*		
Upper/lower flammability or explosive limits	*not determined*		
Vapour pressure	*not determined*		
Vapour density	*not determined*		
Density	*not determined*		
Relative density	*not determined*		
Bulk density	*not determined*		
Water solubility	*not determined*		
Partition coefficient: n-octanol/water	*not determined*		
Dynamic viscosity	*not determined*		
Kinematic viscosity	*not determined*		

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

10.3. Possibility of hazardous reactions
Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

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
Recommended storage temperature: 2-8°C

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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

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 to enter into surface water or drains.

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:

nwg - nicht wassergefährdend

15.2. Chemical Safety Assessment

No data available

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SECTION 16: Other information

16.1. Indication of changes

Überarbeitung gemäß REACH-Verordnung (EG) Nr. 1907/2006, zuletzt geändert durch Verordnung (EU) 2020/878

16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ((Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviairede marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

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. Relevant R-, H- and EUH-phrases (Number and full text)

No data available

16.6. Training advice

No data available

16.7. Additional information

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