Safety Data Sheet
According to Regulation (EG) No. 1907/2006
Revision date: 24.11.2023 Version: 005 replaces version of 14.02.2022

AESKULISA® Immunoassays for Diagnosis of Infectious Diseases

Product Identifier
Product name: **AESKULISA® Immunoassay IgA, IgG or IgM**
Product number: **6xxx**

Test Component	*Symbol*	*Appendix*
Breakable microtiter strips	MP	(1)
Calibrators A – D	CAL	(2)
Positive Control	CON +	(2)
Negative Control	CON –	(2)
Sample dilution buffer, 5x conc.	SB 5x	(3)
Washing buffer, 50x conc.	WASHB 50x	(4)
Anti-human IgA, IgG or IgM conjugate	CON J	(5)
Substrate	SUB	(6)
Stop solution	STOP	(7)

Always read the instructions for use before using the test kit. Terms and conditions apply.
The information in this product data sheet is based on the current state of our knowledge. They do not constitute a guarantee of product characteristics and do not establish a contractual legal relationship.

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

Appendix 1-7
Safety Data Sheets for Individual Components

AESKULISA® Breakable microtiter strips

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

1.1. Product identifier

Trade name/designation:

AESKULISA® Breakable microtiter strips

Other means of identification:
MP

Article No.:
6xxx

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 GmbH & Co.KG
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).

AESKULISA® Breakable microtiter strips

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.

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

AESKULISA® Breakable microtiter strips

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:
Storage temperature: 2-8°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

AESKULISA® Breakable microtiter strips

Safety relevant basis data

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

9.2. Other information
No data available

SECTION 10: Stability and reactivity

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

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

10.3. Possibility of hazardous reactions
No. 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

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.

AESKULISA® Breakable microtiter strips

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

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (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. List of relevant hazard statements and/or precautionary statements from sections 2 to 15
No data available

16.6. Training advice
No data available

16.7. Additional information
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.

AESKULISA ® Calibrators (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 (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

Article No.:
6xxx

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 infection serology. 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 GmbH & Co.KG
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 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.

AESKULISA ® Calibrators (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

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.

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

AESKULISA ® Calibrators (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

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.

AESKULISA ® Calibrators (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

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) from 18 Dec 2011	**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) from 1 May 2010	**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
IOELV (EU) from 17 Dec 2009	**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)

8.1.2. Biological limit values

Limit value type (country of origin)	Substance name	Limit value	① Parameter ② Test material ③ Time of sampling: ④ Remark
TRGS 903 (DE) from 19 Sept 2013	**phenol** CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g Creatinin	① Phenol ② Urin ③ Expositionsende bzw. Schichtende
BLV (EU) from 1 Jun 2014	**phenol** CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

8.1.3. DNEL-/PNEC-values

No data available

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 ® Calibrators (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

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

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn. not relevant

10.2. Chemical stability

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)

AESKULISA ® Calibrators (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

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.

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

AESKULISA ® Calibrators (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

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.
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

AESKULISA ® Calibrators (CAL) AESKULISA ® Positive Control (CON +) AESKULISA ® Negative Control (CON -)

SECTION 15: Regulatory information

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

15.1.1. EU legislation

No data available

15.1.2. National regulations

[DE] National regulations

Water hazard class

WGK:

1 - slightly hazardous to water

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

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

16.2. Abbreviations and acronyms

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

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

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.:
6xxx

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 infection serology. 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 GmbH & Co.KG
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.

AESKULISA ® Sample Dilution Buffer 5x

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.

AESKULISA ® Sample Dilution Buffer 5x

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.

AESKULISA ® Sample Dilution Buffer 5x

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)
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) from 20 Apr 2023	**Natriumazid** CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.2 mg/m³ ② 0.4 mg/m³ ⑤ 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	*No data available*		
Freezing point	*No data available*		
Initial boiling point and boiling range	*No data available*		
Flash point	*not applicable*		
Evaporation rate	*No data available*		

AESKULISA ® Sample Dilution Buffer 5x

Parameter	Value	at °C	① Method ② Remark
Auto-ignition temperature	*not applicable*		
Upper/lower flammability or explosive limits	*No data available*		
Vapour pressure	*No data available*		
Vapour density	*No data available*		
Density	*No data available*		
Bulk density	*not applicable*		
Water solubility	*No data available*		
Dynamic viscosity	*No data available*		
Kinematic viscosity	*No data available*		

9.2. Other information
No data available

SECTION 10: Stability and reactivity

10.1. Reactivity
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.

AESKULISA ® Sample Dilution Buffer 5x

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 - non-hazardous to water

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

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

16.2. Abbreviations and acronyms
°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. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

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.

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.:
6xxx

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 GmbH & Co.KG
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.	

AESKULISA® wash buffer, 50x conc.

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.

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.

AESKULISA® wash buffer, 50x conc.

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: green
Odour: not determined

Safety relevant basis data

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

AESKULISA® wash buffer, 50x conc.

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

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

AESKULISA® wash buffer, 50x conc.

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: Poorly biodegradable.

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.

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

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
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 - obviously hazardous to water

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

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

16.2. Abbreviations and acronyms
°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. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

Hazard statements	
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

16.6. Training advice

No data available

16.7. Additional information

The information is based on the current state of our knowledge. You shall ours Describe products with regard to safety requirements, but do not represent them Assurance of product properties and do not constitute a contractual legal relationship.

AESKULISA ® anti human IgX conjugate

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

1.1. Product identifier

Trade name/designation:

AESKULISA ® anti human IgX conjugate

Other means of identification:

CONJ

Article No.:

6xxx

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 GmbH & Co.KG
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

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.

AESKULISA ® anti human IgX conjugate

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

5.3. Advice for firefighters

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

AESKULISA ® anti human IgX conjugate

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.

AESKULISA ® anti human IgX conjugate

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) from 18 Dec 2011	**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) from 1 May 2010	**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
IOELV (EU) from 17 Dec 2009	**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)

8.1.2. Biological limit values

Limit value type (country of origin)	Substance name	Limit value	① Parameter ② Test material ③ Time of sampling: ④ Remark
TRGS 903 (DE) from 19 Sept 2013	**phenol** CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g Creatinin	① Phenol ② Urin ③ Expositionsende bzw. Schichtende
BLV (EU) from 1 Jun 2014	**phenol** CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

8.1.3. DNEL-/PNEC-values

No data available

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

AESKULISA ® anti human IgX conjugate

Odour: not determined

Safety relevant basis data

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

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product itself does not burn. not relevant

10.2. Chemical stability

Storage temperature: 2-8°C

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

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

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)

AESKULISA ® anti human IgX conjugate

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

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: Poorly biodegradable.

phenol CAS No.: 108-95-2 EC No.: 203-632-7
Biodegradation: Yes, rapidly

12.3. Bioaccumulative potential

phenol CAS No.: 108-95-2 EC No.: 203-632-7
Log K_{OW}: 1.47
Bioconcentration factor (BCF): 17.5

12.4. Mobility in soil
No data available

AESKULISA ® anti human IgX conjugate

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.

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

AESKULISA ® anti human IgX conjugate

SECTION 15: Regulatory information

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

15.1.1. EU legislation

No data available

15.1.2. National regulations

[DE] National regulations

Water hazard class

WGK:

1 - slightly hazardous to water

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

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

16.2. Abbreviations and acronyms

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

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

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.:
6xxx

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 GmbH & Co.KG
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

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.

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.

AESKULISA® Substrate

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

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

AESKULISA® Substrate

Safety relevant basis data

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

9.2. Other information
No data available

SECTION 10: Stability and reactivity

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

10.2. Chemical stability
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.

AESKULISA® Substrate

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 - non-hazardous to water

15.2. Chemical Safety Assessment
No data available

SECTION 16: Other information

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

16.2. Abbreviations and acronyms
°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. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

No data available

16.6. Training advice

No data available

16.7. Additional information

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.

AESKULISA® Stop solution

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

1.1. Product identifier

Trade name/designation:

AESKULISA® Stop solution

Other means of identification:
STOP

Article No.:
6xxx

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 GmbH & Co.KG
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.

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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

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
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.

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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.

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

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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
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
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)
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)

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: 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	*No data available*		

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

9.2. Other information
No data available

SECTION 10: Stability and reactivity

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

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

10.3. Possibility of hazardous reactions
No data available

10.4. Conditions to avoid
No data available

10.5. Incompatible materials
No data available

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

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)

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

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.

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SECTION 14: Transport information

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

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

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

16.2. Abbreviations and acronyms

°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)

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

16.3. Key literature references and sources for data

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

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.