**Safety Data Sheet**
according to Regulation (EC) No 1907/2006
Valid from:01.01.2023 Version: 006 replaces version of 08.02.2022

## *AESKULISA® Autoimmunity*

**Product identifier**
Item name: ***AESKULISA®* Autoimmunity**
Item number: **3xxx***

| *Test Component* | *Abbreviation / Symbol* | *Attachment* |
|---|---|---|
| **Breakable microtiter strips** | MP | (1) |
| **Calibrators A – F** | CAL | (2) |
| **Cut-off calibrator** | CO-CAL | (2) |
| **Positive control** | CON + | (2) |
| **Negative control** | CON – | (2) |
| **Sample dilution buffer, 5x conc.** | SB 5x | (3) |
| **Wash buffer, 50x conc.** | WASHB 50x | (4) |
| **Anti-Human IgA, IgG or IgM conjugate** | CON J | (5) |
| **Substrate** | SUB | (6) |
| **Stop Solution** | STOP | (7) |
| **Recovery**** | RC | (8) |

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

** only in ref 3402

Always read the instructions for use before using the test kit. The General Terms and Conditions.

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

Copyright©: Aesku.Diagnostics GmbH & Co. KG, copies may only be made for internal use.

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

**Appendix 1-8**
Safety data sheets for individual components

# AESKULISA® Break apart microtiter test strips

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

### 1.1. Product identifier

**Trade name/designation:**

AESKULISA® Break apart microtiter test strips

**Other means of identification:**

MP

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

AESKULISA®

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

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

**Manufacturer:**


**AESKU.DIAGNOSTICS 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).

### 2.3. Other hazards

**Adverse physicochemical effects:**

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

# AESKULISA® Break apart microtiter test strips

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures
No data available

## SECTION 4: First aid measures

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

**Following inhalation:**
Provide fresh air.

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

### 4.2. Most important symptoms and effects, both acute and delayed
No known symptoms to date.

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

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media
**Suitable extinguishing media:**
Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture
The product itself does not burn.

**Hazardous combustion products:**
In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters
Wear a self-contained breathing apparatus and chemical protective clothing.

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

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures
### 6.1.1. For non-emergency personnel
**Personal precautions:**
Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

**Protective equipment:**
Wear protective gloves/protective clothing/eye protection/face protection.

### 6.1.2. For emergency responders
**Personal protection equipment:**
Personal protection equipment: see section 8

### 6.2. Environmental precautions
Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up
**For containment:**
Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

# AESKULISA® Break apart microtiter test strips

### 6.4. Reference to other sections
Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information
Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Protective measures**

**Advices on safe handling:**
Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**
No special measures are necessary.

**Advices on general occupational hygiene**
When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

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

**Technical measures and storage conditions:**
Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**
Lagerung bei +2°C bis +8°C.

### 7.3. Specific end use(s)
No data available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters
No data available

### 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls
No data available

### 8.2.2. Personal protection equipment

**Eye/face protection:**
Eye glasses with side protection EN 166

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

### 8.2.3. Environmental exposure controls
No data available

## SECTION 9: Physical and chemical properties

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

**Appearance**

**Physical state:** solid:
**Colour:** whitish
**Odour:** not determined

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

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

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

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

### 10.5. Incompatible materials
No data available

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

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008
**Acute oral toxicity:**
Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**
Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**
Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**
Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:**
Based on available data, the classification criteria are not met.

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

**Reproductive toxicity:**
Based on available data, the classification criteria are not met.

**STOT-single exposure:**
Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**
Based on available data, the classification criteria are not met.

**Aspiration hazard:**
Based on available data, the classification criteria are not met.

**Additional information:**
No data available

### 11.2. Information on other hazards
No data available

## SECTION 12: Ecological information

### 12.1. Toxicity
No data available

### 12.2. Persistence and degradability
No data available

### 12.3. Bioaccumulative potential
No data available

### 12.4. Mobility in soil
No data available

# AESKULISA® Break apart microtiter test strips

### 12.5. Results of PBT and vPvB assessment
No data available

### 12.6. Endocrine disrupting properties
No data available

### 12.7. Other adverse effects
No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

### 13.1.1. Product/Packaging disposal

### Waste codes/waste designations according to EWC/AVV
**Waste code product**

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

### Waste treatment options
**Appropriate disposal / Product:**
Consult the appropriate local waste disposal expert about waste disposal.

## SECTION 14: Transport information

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

### 14.7. Maritime transport in bulk according to IMO instruments
No data available

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available

### 15.2. Chemical Safety Assessment
No data available

## SECTION 16: Other information

### 16.1. Indication of changes
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. Relevant R-, H- and EUH-phrases (Number and full text)

No data available

### 16.6. Training advice

No data available

### 16.7. Additional information

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



GeSi.de

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

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

### 1.1. Product identifier

**Trade name/designation:**

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

**Article No.:**
3xxx

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

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

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

**Manufacturer:**

**AESKU.DIAGNOSTICS 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.




GeSi.de

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

**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<br>Classification according to Regulation (EC) No 1272/2008 [CLP] | Concentration |
|---|---|---|
| | **ProClin ® 300**<br>Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317)<br> Danger | 0 – < 0.1 weight-% |
| CAS No.: 108-95-2<br>EC No.: 203-632-7<br>Index No.: 604-001-00-2 | **phenol**<br>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)<br> Danger<br>**Specific concentration limit (SCL)**<br>Skin Corr. 1B; H314: C ≥ 3%<br>Skin Irrit. 2; H315: 1% ≤ C < 3%<br>Eye Dam. 1; H318: C ≥ 3%<br>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.

## 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 A-F (CAL) AESKULISA ® Cut-off Calibrator (CO-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<br>② Short-term occupational exposure limit value<br>③ Instantaneous value<br>④ Monitoring and observation processes<br>⑤ Remark |
|---|---|---|
| WEL (GB)<br>from 18 Dec 2011 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (7.8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (may be absorbed through the skin) |
| IDLH (US)<br>from 1 Jan 1994 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 250 ppm |
| TRGS 900 (DE)<br>from 1 May 2010 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11 |
| ES<br>from 1 Jan 2012 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI |
| IOELV (EU)<br>from 17 Dec 2009 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (may be absorbed through the skin) |
| VRC (FR) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (7.8 mg/m³)<br>② 4 ppm (15.6 mg/m³)<br>⑤ (peut être absorbé par la peau) |
| GR<br>from 1 Oct 2016 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (αναμένετε απορρόφηση από το δέρμα) |
| OSHA (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>⑤ (may be absorbed through the skin) |
| NIOSH (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>③ 15.6 ppm (60 mg/m³)<br>⑤ (may be absorbed through the skin) |
| ACGIH (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>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<br>② Test material<br>③ Time of sampling:<br>④ Remark |
|---|---|---|---|
| TRGS 903 (DE)<br>from 19 Sept 2013 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>Creatinin | ① Phenol<br>② Urin<br>③ Expositionsende bzw. Schichtende |
| VLB (ES)<br>from 1 Jan 2013 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>creatinina | ① fenol<br>② orina<br>③ fin de exposición o fin de turno |
| ACGIH-BEI (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 250 mg/g<br>creatinine | ① phenol<br>② urine<br>③ end of exposure or end of shift |
| BLV (EU)<br>from 1 Jun 2014 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>creatinine | ① phenol<br>② urine<br>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:** yellow-orange
**Odour:** not determined

### Safety relevant basis data

| Parameter | Value | at °C | ① Method<br>② Remark |
|---|---|---|---|
| pH | 6.7 – 6.9 | 21 °C | |
| Melting point | *not determined* | | |
| Freezing point | *not determined* | | |
| Initial boiling point and boiling range | *not determined* | | |
| Decomposition temperature | *not determined* | | |
| Flash point | *not determined* | | |
| Evaporation rate | *not determined* | | |
| Auto-ignition temperature | *not determined* | | |

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

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

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

### 10.3. Possibility of hazardous reactions
No known hazardous reactions.

### 10.4. Conditions to avoid
Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials
No data available

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

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

## SECTION 11: Toxicological information

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

| **phenol** CAS No.: 108-95-2 EC No.: 203-632-7 |
|---|
| **$LD_{50}$ oral:** 317 mg/kg (Ratte) |
| **$LD_{50}$ dermal:** 630 mg/kg (Kaninchen) |

**Acute oral toxicity:**
Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**
Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**
Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**
Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:**
Based on available data, the classification criteria are not met.

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

**Reproductive toxicity:**
Based on available data, the classification criteria are not met.

**STOT-single exposure:**
Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**
Based on available data, the classification criteria are not met.

**Aspiration hazard:**
Based on available data, the classification criteria are not met.

**Additional information:**
No data available

### 11.2. Information on other hazards

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

## SECTION 12: Ecological information

### 12.1. Toxicity

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

### 12.2. Persistence and degradability

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

### 12.3. Bioaccumulative potential

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

### 12.4. Mobility in soil
No data available

### 12.5. Results of PBT and vPvB assessment

| **phenol** CAS No.: 108-95-2 EC No.: 203-632-7 |
|---|
| **Results of PBT and vPvB assessment:** This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII. |

### 12.6. Endocrine disrupting properties
No data available

### 12.7. Other adverse effects
No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

### 13.1.1. Product/Packaging disposal

**Waste codes/waste designations according to EWC/AVV**

**Waste code product**

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

**Waste treatment options**

**Appropriate disposal / Product:**

Consult the appropriate local waste disposal expert about waste disposal.

## SECTION 14: Transport information

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

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

### 15.1.1. EU legislation

No data available

### 15.1.2. National regulations

**[DE] National regulations**

**Water hazard class**

**WGK:**

1 - schwach wassergefährdend

### 15.2. Chemical Safety Assessment

No data available

## SECTION 16: Other information

### 16.1. Indication of changes

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

| **Hazard statements** | |
|---|---|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |

| Hazard statements | |
|---|---|
| H311 | Toxic in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H331 | Toxic if inhaled. |
| H341 | Suspected of causing genetic defects. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |

## 16.6. Training advice

No data available

## 16.7. Additional information

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

# AESKULISA ® Sample Dilution Buffer 5x

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

### 1.1. Product identifier

**Trade name/designation:**

AESKULISA ® Sample Dilution Buffer 5x

**Other means of identification:**

SB 5x

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

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

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

**Manufacturer:**


**AESKU.DIAGNOSTICS 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.

**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.

## AESKULISA ® Sample Dilution Buffer 5x

**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<br>Classification according to Regulation (EC) No 1272/2008 [CLP] | Concentration |
|---|---|---|
| CAS No.: 26628-22-8<br>EC No.: 247-852-1<br>REACH No.:<br>01-2119457019-37 | **Natriumazid**<br>Acute Tox. 1 (H310), Acute Tox. 2 (H300, H330),<br>Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), STOT RE 2 (H373)<br> Danger | 0.01 – ≤ 0.05 weight-% |

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

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

**Following inhalation:**
Provide fresh air.

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

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

No known symptoms to date.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable extinguishing media:**
Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

**Hazardous combustion products:**
In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

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

### 5.4. Additional information

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

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

**Personal precautions:**
Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

**Protective equipment:**
Wear protective gloves/protective clothing/eye protection/face protection.

# AESKULISA ® Sample Dilution Buffer 5x

### 6.1.2. For emergency responders

**Personal protection equipment:**
Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

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

### 6.4. Reference to other sections

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

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

### Protective measures

**Advices on safe handling:**
Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**
No special measures are necessary.

### Advices on general occupational hygiene

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

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

**Technical measures and storage conditions:**
Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**
Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

**Recommendation:**
Item 1.2 and the instructions for use must be observed.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### 8.1.1. Occupational exposure limit values

| **Limit value type (country of origin)** | **Substance name** | **① Long-term occupational exposure limit value<br>② Short-term occupational exposure limit value<br>③ Instantaneous value<br>④ Monitoring and observation processes<br>⑤ Remark** |
|---|---|---|
| WEL (GB) | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ① 0.1 mg/m³<br>② 0.3 mg/m³<br>⑤ (may be absorbed through the skin) |
| ES | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ① 0.1 mg/m³<br>② 0.3 mg/m³<br>⑤ (puede ser absorbido a través dérmica) vía dérmica, VLI |
| VRC (FR)<br>from 3 May 2021 | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ① 0.1 mg/m³<br>② 0.3 mg/m³<br>⑤ (peut être absorbé par la peau) |

## AESKULISA ® Sample Dilution Buffer 5x

| Limit value type (country of origin) | Substance name | ① Long-term occupational exposure limit value<br>② Short-term occupational exposure limit value<br>③ Instantaneous value<br>④ Monitoring and observation processes<br>⑤ Remark |
|---|---|---|
| ACGIH (US) | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ③ 0.29 mg/m³<br>⑤ (as Sodium azide) |
| NIOSH (US) | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ③ 0.1 ppm<br>⑤ (as HN3; may be absorbed through the skin) |
| GR<br>from 1 Oct 2016 | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ① 0.1 ppm (0.3 mg/m³)<br>② 0.1 ppm (0.3 mg/m³) |
| NIOSH (US) | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ③ 0.3 mg/m³<br>⑤ (as NaN3; may be absorbed through the skin) |
| ACGIH (US) | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ③ 0.11 ppm<br>⑤ (as Hydrazoic acid vapour) |
| IOELV (EU) | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ① 0.1 mg/m³<br>② 0.3 mg/m³<br>⑤ (may be absorbed through the skin) |
| TRGS 900 (DE) | **Natriumazid**<br>CAS No.: 26628-22-8<br>EC No.: 247-852-1 | ① 0.2 mg/m³<br>② 0.4 mg/m³<br>⑤ (einatembare Fraktion) DFG, EU |

### 8.1.2. Biological limit values
No data available

### 8.1.3. DNEL-/PNEC-values
No data available

### 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls
No data available

### 8.2.2. Personal protection equipment

**Eye/face protection:**
Eye glasses with side protection EN 166

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

### 8.2.3. Environmental exposure controls
No data available

## SECTION 9: Physical and chemical properties

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

### Appearance

**Physical state:** Liquid
**Colour:** yellow
**Odour:** not determined

## AESKULISA ® Sample Dilution Buffer 5x

### Safety relevant basis data

| Parameter | Value | at °C | ① Method<br>② Remark |
|---|---|---|---|
| pH | 7.4 – 7.6 | 21 °C | |
| Melting point | *not determined* | | |
| Freezing point | *not determined* | | |
| Initial boiling point and boiling range | *not determined* | | |
| Decomposition temperature | *not determined* | | |
| Flash point | *not determined* | | |
| Evaporation rate | *not determined* | | |
| Auto-ignition temperature | *not determined* | | |
| Upper/lower flammability or explosive limits | *not determined* | | |
| Vapour pressure | *not determined* | | |
| Vapour density | *not determined* | | |
| Density | *not determined* | | |
| Relative density | *not determined* | | |
| Bulk density | *not determined* | | |
| Water solubility | *not determined* | | |
| Partition coefficient: n-octanol/water | *not determined* | | |
| Dynamic viscosity | *not determined* | | |
| Kinematic viscosity | *not determined* | | |

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

### 10.2. Chemical stability
No data available

### 10.3. Possibility of hazardous reactions
No data available

### 10.4. Conditions to avoid
No data available

### 10.5. Incompatible materials
No data available

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

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

## SECTION 11: Toxicological information

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

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

**Acute oral toxicity:**
Based on available data, the classification criteria are not met.

## AESKULISA ® Sample Dilution Buffer 5x

**Acute dermal toxicity:**
Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**
Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**
Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:**
Based on available data, the classification criteria are not met.

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

**Reproductive toxicity:**
Based on available data, the classification criteria are not met.

**STOT-single exposure:**
Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**
Based on available data, the classification criteria are not met.

**Aspiration hazard:**
Based on available data, the classification criteria are not met.

**Additional information:**
No data available

### 11.2. Information on other hazards
No data available

## SECTION 12: Ecological information

### 12.1. Toxicity

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

### 12.2. Persistence and degradability
No data available

### 12.3. Bioaccumulative potential
No data available

### 12.4. Mobility in soil
No data available

### 12.5. Results of PBT and vPvB assessment

| **Natriumazid** CAS No.: 26628-22-8 EC No.: 247-852-1 |
|---|
| **Results of PBT and vPvB assessment:** This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII. |

### 12.6. Endocrine disrupting properties
No data available

### 12.7. Other adverse effects
No data available

## AESKULISA ® Sample Dilution Buffer 5x

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

### 13.1.1. Product/Packaging disposal

**Waste codes/waste designations according to EWC/AVV**

**Waste code product**

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

**Waste treatment options**

**Appropriate disposal / Product:**

Consult the appropriate local waste disposal expert about waste disposal.

### 13.2. Additional information

Do not allow to enter into surface water or drains.

## SECTION 14: Transport information

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

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

### 15.1.1. EU legislation

No data available

### 15.1.2. National regulations

**[DE] National regulations**

**Water hazard class**

**WGK:**

nwg - nicht wassergefährdend

### 15.2. Chemical Safety Assessment

No data available




GeSi.de

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

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

### 16.6. Training advice
No data available

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

# AESKULISA® wash buffer, 50x conc.

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

### 1.1. Product identifier

**Trade name/designation:**

AESKULISA® wash buffer, 50x conc.

**Other means of identification:**

WASHB 50x

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

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

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

**Manufacturer:**


**AESKU.DIAGNOSTICS 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. | |

### 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 .... |

# AESKULISA® wash buffer, 50x conc.

### 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<br>Classification according to Regulation (EC) No 1272/2008 [CLP] | Concentration |
|---|---|---|
| | **ProClin ® 300**<br>Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1B (H314), Skin Sens. 1 (H317)<br> 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.


GeSi.de

# AESKULISA® wash buffer, 50x conc.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

**Personal precautions:**
Remove persons to safety.

**Protective equipment:**
Wear protective gloves/protective clothing/eye protection/face protection.

#### 6.1.2. For emergency responders

**Personal protection equipment:**
Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

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

### 6.4. Reference to other sections

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

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

**Advices on safe handling:**
Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**
No special measures are necessary.

#### Advices on general occupational hygiene

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

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

**Technical measures and storage conditions:**
Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**
Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

**Recommendation:**
Item 1.2 and the instructions for use must be observed.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

**Eye/face protection:**
Eye glasses with side protection EN 166

**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<br>② Remark |
|---|---|---|---|
| pH | 7.4 – 7.8 | 21 °C | |
| Melting point | *not determined* | | |
| Freezing point | *not determined* | | |
| Initial boiling point and boiling range | *not determined* | | |
| Decomposition temperature | *not determined* | | |
| Flash point | *not determined* | | |
| Evaporation rate | *not determined* | | |
| Auto-ignition temperature | *not determined* | | |
| Upper/lower flammability or explosive limits | *not determined* | | |
| Vapour pressure | *not determined* | | |
| Vapour density | *not determined* | | |
| Density | *not determined* | | |
| Relative density | *not determined* | | |
| Bulk density | *not determined* | | |
| Water solubility | *not determined* | | |
| Partition coefficient: n-octanol/water | *not determined* | | |
| Dynamic viscosity | *not determined* | | |
| Kinematic viscosity | *not determined* | | |

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

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

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

### 10.4. Conditions to avoid
Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials
No data available

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

## AESKULISA® wash buffer, 50x conc.

## SECTION 11: Toxicological information

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

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

**Acute oral toxicity:**
Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**
Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**
Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**
Contains ProClin ® 300. May produce an allergic reaction.

**Germ cell mutagenicity:**
Based on available data, the classification criteria are not met.

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

**Reproductive toxicity:**
Based on available data, the classification criteria are not met.

**STOT-single exposure:**
Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**
Based on available data, the classification criteria are not met.

**Aspiration hazard:**
Based on available data, the classification criteria are not met.

**Additional information:**
No data available

### 11.2. Information on other hazards
No data available

## SECTION 12: Ecological information

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

### 12.2. Persistence and degradability

| ProClin ® 300 |
|---|
| **Biodegradation:** 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 |
| **14.5. Environmental hazards** | | | |
| not relevant | not relevant | not relevant | not relevant |
| **14.6. Special precautions for user** | | | |
| not relevant | not relevant | not relevant | not relevant |

### 14.7. Maritime transport in bulk according to IMO instruments
No data available

## SECTION 15: Regulatory information

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

### 15.1.1. EU legislation
No data available

### 15.1.2. National regulations
**[DE] National regulations**

**Water hazard class**

**WGK:**
2 - deutlich wassergefährdend

### 15.2. Chemical Safety Assessment
No data available

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

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

### 16.6. Training advice

No data available

### 16.7. Additional information

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

# AESKULISA ® anti human 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.:**

3xxx

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

**Use of the substance/mixture:**

AESKULISA®

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

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

**Manufacturer:**


**AESKU.DIAGNOSTICS 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.

**Adverse environmental effects:**

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




GeSi.de

## AESKULISA ® anti human IgX conjugate

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

**Hazardous ingredients / Hazardous impurities / Stabilisers:**

| Product identifiers | Substance name<br>Classification according to Regulation (EC) No 1272/2008 [CLP] | Concentration |
|---|---|---|
| | **ProClin ® 300**<br>Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317)<br> Danger | 0 – ≤ 0.1 weight-% |
| CAS No.: 108-95-2<br>EC No.: 203-632-7<br>Index No.: 604-001-00-2 | **phenol**<br>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)<br> Danger<br>**Specific concentration limit (SCL)**<br>Skin Corr. 1B; H314: C ≥ 3%<br>Skin Irrit. 2; H315: 1% ≤ C < 3%<br>Eye Dam. 1; H318: C ≥ 3%<br>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 ® anti human IgX conjugate

## 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<br>② Short-term occupational exposure limit value<br>③ Instantaneous value<br>④ Monitoring and observation processes<br>⑤ Remark |
|---|---|---|
| WEL (GB)<br>from 18 Dec 2011 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (7.8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (may be absorbed through the skin) |
| IDLH (US)<br>from 1 Jan 1994 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 250 ppm |
| TRGS 900 (DE)<br>from 1 May 2010 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11 |
| ES<br>from 1 Jan 2012 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI |
| IOELV (EU)<br>from 17 Dec 2009 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (may be absorbed through the skin) |
| VRC (FR) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (7.8 mg/m³)<br>② 4 ppm (15.6 mg/m³)<br>⑤ (peut être absorbé par la peau) |
| GR<br>from 1 Oct 2016 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (αναμένετε απορρόφηση από το δέρμα) |
| OSHA (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>⑤ (may be absorbed through the skin) |
| NIOSH (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>③ 15.6 ppm (60 mg/m³)<br>⑤ (may be absorbed through the skin) |
| ACGIH (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>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<br>② Test material<br>③ Time of sampling:<br>④ Remark |
|---|---|---|---|
| TRGS 903 (DE)<br>from 19 Sept 2013 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>Creatinin | ① Phenol<br>② Urin<br>③ Expositionsende bzw. Schichtende |
| VLB (ES)<br>from 1 Jan 2013 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>creatinina | ① fenol<br>② orina<br>③ fin de exposición o fin de turno |
| ACGIH-BEI (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 250 mg/g<br>creatinine | ① phenol<br>② urine<br>③ end of exposure or end of shift |
| BLV (EU)<br>from 1 Jun 2014 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>creatinine | ① phenol<br>② urine<br>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
**Odour:** not determined

### Safety relevant basis data

| Parameter | Value | at °C | ① Method<br>② Remark |
|---|---|---|---|
| pH | 6.7 – 6.9 | 21 °C | |
| Melting point | *not determined* | | |
| Freezing point | *not determined* | | |
| Initial boiling point and boiling range | *not determined* | | |
| Decomposition temperature | *not determined* | | |
| Flash point | *not determined* | | |
| Evaporation rate | *not determined* | | |
| Auto-ignition temperature | *not determined* | | |
| Upper/lower flammability or explosive limits | *not determined* | | |



GeSi.de

## AESKULISA ® anti human IgX conjugate

| Parameter | Value | at °C | ① Method<br>② Remark |
|---|---|---|---|
| Vapour pressure | *not determined* | | |
| Vapour density | *not determined* | | |
| Density | *not determined* | | |
| Relative density | *not determined* | | |
| Bulk density | *not determined* | | |
| Water solubility | *not determined* | | |
| Partition coefficient: n-octanol/water | *not determined* | | |
| Dynamic viscosity | *not determined* | | |
| Kinematic viscosity | *not determined* | | |

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

### 10.2. Chemical stability
Empfohlenen Lagertemperatur: 2-8°C.

### 10.3. Possibility of hazardous reactions
No data available

### 10.4. Conditions to avoid
Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials
No data available

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

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

## SECTION 11: Toxicological information

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

| **ProClin ® 300** |
|---|
| **$LD_{50}$ oral:** 862 mg/kg (Ratte) |
| **$LD_{50}$ dermal:** 2,800 mg/kg (Kaninchen) |
| **phenol** CAS No.: 108-95-2 EC No.: 203-632-7 |
| **$LD_{50}$ oral:** 317 mg/kg (Ratte) |
| **$LD_{50}$ dermal:** 630 mg/kg (Kaninchen) |

**Acute oral toxicity:**
Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**
Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**
Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.



GeSi.de

**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

### 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

## AESKULISA ® anti human IgX conjugate

## 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

## SECTION 15: Regulatory information

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

### 15.1.1. EU legislation

No data available

### 15.1.2. National regulations

**[DE] National regulations**

**Water hazard class**

**WGK:**

1 - schwach wassergefährdend

### 15.2. Chemical Safety Assessment

No data available




GeSi.de

# AESKULISA ® anti human IgX conjugate

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

| Hazard statements | |
|---|---|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |
| H311 | Toxic in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H331 | Toxic if inhaled. |
| H341 | Suspected of causing genetic defects. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |

### 16.6. Training advice
No data available

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


GeSi.de

# AESKULISA® Substrate

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

### 1.1. Product identifier

**Trade name/designation:**

AESKULISA® Substrate

**Other means of identification:**

SUB

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

AESKULISA®

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

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

**Manufacturer:**


**AESKU.DIAGNOSTICS 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




GeSi.de

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

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

**Following inhalation:**
Provide fresh air.

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

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

No known symptoms to date.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable extinguishing media:**
Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

**Hazardous combustion products:**
In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

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

### 5.4. Additional information

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

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

**Personal precautions:**
Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

**Protective equipment:**
Wear protective gloves/protective clothing/eye protection/face protection.

#### 6.1.2. For emergency responders

**Personal protection equipment:**
Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

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

### 6.4. Reference to other sections

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

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## AESKULISA® Substrate

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Protective measures**

**Advices on safe handling:**
Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**
No special measures are necessary.

**Advices on general occupational hygiene**
When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

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

**Technical measures and storage conditions:**
Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**
Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

**Recommendation:**
Item 1.2 and the instructions for use must be observed.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters
No data available

### 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls
No data available

### 8.2.2. Personal protection equipment

**Eye/face protection:**
Eye glasses with side protection EN 166

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

### 8.2.3. Environmental exposure controls
No data available

## SECTION 9: Physical and chemical properties

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

**Appearance**

**Physical state:** Liquid
**Colour:** clear
**Odour:** not determined

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

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

### 10.3. Possibility of hazardous reactions
No data available

# AESKULISA® Substrate

### 10.4. Conditions to avoid
Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials
No data available

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

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

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008
**Acute oral toxicity:**
Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**
Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**
Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**
Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:**
Based on available data, the classification criteria are not met.

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

**Reproductive toxicity:**
Based on available data, the classification criteria are not met.

**STOT-single exposure:**
Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**
Based on available data, the classification criteria are not met.

**Aspiration hazard:**
Based on available data, the classification criteria are not met.

**Additional information:**
No data available

### 11.2. Information on other hazards
No data available

## SECTION 12: Ecological information

### 12.1. Toxicity
No data available

### 12.2. Persistence and degradability
No data available

### 12.3. Bioaccumulative potential
No data available

### 12.4. Mobility in soil
No data available

### 12.5. Results of PBT and vPvB assessment
No data available

# AESKULISA® Substrate

### 12.6. Endocrine disrupting properties
No data available

### 12.7. Other adverse effects
No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

### 13.1.1. Product/Packaging disposal

**Waste codes/waste designations according to EWC/AVV**

**Waste code product**

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

**Waste treatment options**

**Appropriate disposal / Product:**
Consult the appropriate local waste disposal expert about waste disposal.

### 13.2. Additional information
Do not allow to enter into surface water or drains.

## SECTION 14: Transport information

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

### 14.7. Maritime transport in bulk according to IMO instruments
No data available

## SECTION 15: Regulatory information

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

### 15.1.1. EU legislation
No data available

### 15.1.2. National regulations

**[DE] National regulations**

**Water hazard class**

**WGK:**
nwg - nicht wassergefährdend


GeSi.de

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

No data available

### 16.6. Training advice

No data available

### 16.7. Additional information

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

# AESKULISA® Stop

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

### 1.1. Product identifier

**Trade name/designation:**

AESKULISA® Stop

**Other means of identification:**

STOP

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

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

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

**Manufacturer:**


**AESKU.DIAGNOSTICS 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. |

## AESKULISA® Stop

**Supplemental hazard information:** none

| Precautionary statements Prevention | |
|---|---|
| P234 | Keep only in original packaging. |

| Precautionary statements Response | |
|---|---|
| P390 | Absorb spillage to prevent material damage. |

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

### 2.3. Other hazards

**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<br>Classification according to Regulation (EC) No 1272/2008 [CLP] | Concentration |
|---|---|---|
| CAS No.: 7647-01-0<br>EC No.: 231-595-7<br>Index No.: 017-002-01-X | **hydrogen chloride**<br>Met. Corr. 1 (H290), STOT SE 3 (H335), Skin Corr. 1B (H314)<br> Danger<br>**Specific concentration limit (SCL)**<br>Met. Corr. 1; H290: C ≥ 0.1%<br>Skin Corr. 1B; H314: C ≥ 25%<br>Skin Irrit. 2; H315: 10% ≤ C < 25%<br>Eye Dam. 1; H318: C ≥ 25%<br>Eye Irrit. 2; H319: 10% ≤ C < 25%<br>STOT SE 3; H335: C ≥ 10% | 1 – ≤ 3<br>weight-% |

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

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

**Following inhalation:**
Provide fresh air. In case of respiratory tract irritation, consult a physician.

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

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

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

No data available

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable extinguishing media:**
Co-ordinate fire-fighting measures to the fire surroundings.

# AESKULISA® Stop

### 5.2. Special hazards arising from the substance or mixture
The product itself does not burn.

**Hazardous combustion products:**
In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters
Wear a self-contained breathing apparatus and chemical protective clothing.

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

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures
### 6.1.1. For non-emergency personnel
**Personal precautions:**
Remove persons to safety.

**Protective equipment:**
Wear protective gloves/protective clothing/eye protection/face protection.

### 6.1.2. For emergency responders
**Personal protection equipment:**
Personal protection equipment: see section 8

### 6.2. Environmental precautions
Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up
**For containment:**
Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

### 6.4. Reference to other sections
Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information
Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling
### Protective measures
**Advices on safe handling:**
Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**
No special measures are necessary.

### Advices on general occupational hygiene
When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities
**Technical measures and storage conditions:**
Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**
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® Stop

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1. Occupational exposure limit values

| Limit value type (country of origin) | Substance name | ① Long-term occupational exposure limit value<br>② Short-term occupational exposure limit value<br>③ Instantaneous value<br>④ Monitoring and observation processes<br>⑤ Remark |
|---|---|---|
| TRGS 900 (DE) | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ① 2 ppm (3 mg/m³)<br>② 4 ppm (6 mg/m³)<br>⑤ (Chlorwasserstoff) DFG, EU, Y |
| ES | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ① 5 ppm (7.6 mg/m³)<br>② 10 ppm (15 mg/m³)<br>⑤ VLI |
| IOELV (EU) | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ① 5 ppm (8 mg/m³)<br>② 10 ppm (15 mg/m³)<br>⑤ (Hydrogen chloride) |
| VRC (FR) | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ② 5 ppm (7.6 mg/m³)<br>⑤ (chlorure d'hydrogéne) |
| WEL (GB) | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ① 1 ppm (2 mg/m³)<br>② 5 ppm (8 mg/m³)<br>⑤ (gas and aerosol mists) |
| GR<br>from 1 Oct 2016 | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ① 5 ppm (7 mg/m³)<br>② 5 ppm (7 mg/m³)<br>⑤ (υδροχλώριο) |
| IDLH (US)<br>from 1 Jan 1994 | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ① 50 ppm |
| OSHA (US) | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ③ 5 ppm (7 mg/m³) |
| NIOSH (US) | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ③ 5 ppm (7 mg/m³) |
| ACGIH (US)<br>from 1 Mar 2014 | **hydrogen chloride**<br>CAS No.: 7647-01-0<br>EC No.: 231-595-7 | ③ 2 ppm (2.98 mg/m³)<br>⑤ (A4) |

#### 8.1.2. Biological limit values
No data available

#### 8.1.3. DNEL-/PNEC-values
No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls
No data available

#### 8.2.2. Personal protection equipment
**Eye/face protection:**
Eye glasses with side protection EN 166

## AESKULISA® Stop

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

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

### 10.2. Chemical stability
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

## AESKULISA® Stop

## 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



GeSi.de

### 12.7. Other adverse effects
No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

### 13.1.1. Product/Packaging disposal

### Waste codes/waste designations according to EWC/AVV
**Waste code product**

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

### Waste treatment options
**Appropriate disposal / Product:**
Consult the appropriate local waste disposal expert about waste disposal.

## SECTION 14: Transport information

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

### 14.7. Maritime transport in bulk according to IMO instruments
No data available

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available

### 15.2. Chemical Safety Assessment
No data available

## SECTION 16: Other information

### 16.1. Indication of changes
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)



GeSi.de

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

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

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

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

UN United Nations

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

## 16.3. Key literature references and sources for data

No data available

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

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

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

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

### 16.6. Training advice
No data available

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


GeSi.de

# AESKULISA® Recovery

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

### 1.1. Product identifier

**Trade name/designation:**

AESKULISA® Recovery

**Other means of identification:**

RC

**Article No.:**

3402

### 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 | |
|---|---|
| EUH208 | Contains ProClin ® 300. May produce an allergic reaction. |

**Precautionary statements:** none

### 2.3. Other hazards

**Adverse environmental effects:**

The substance in the mixture does not meet the PBT/vPvB criteria according to REACH, annex XIII.

**Other adverse effects:**

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

## AESKULISA® Recovery

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

**Hazardous ingredients / Hazardous impurities / Stabilisers:**

| Product identifiers | Substance name<br>Classification according to Regulation (EC) No 1272/2008 [CLP] | Concentration |
|---|---|---|
| | **ProClin ® 300**<br>Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317)<br> Danger | 0 – ≤ 0.1 weight-% |
| CAS No.: 108-95-2<br>EC No.: 203-632-7<br>Index No.: 604-001-00-2 | **phenol**<br>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)<br> Danger<br>**Specific concentration limit (SCL)**<br>Skin Corr. 1B; H314: C ≥ 3%<br>Skin Irrit. 2; H315: 1% ≤ C < 3%<br>Eye Dam. 1; H318: C ≥ 3%<br>Eye Irrit. 2; H319: 1% ≤ C < 3% | 0 – < 0.01 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® Recovery

## 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.

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

**Further information on storage conditions:**
Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

**Recommendation:**
Item 1.2 and the instructions for use must be observed.

## AESKULISA® Recovery

## 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<br>② Short-term occupational exposure limit value<br>③ Instantaneous value<br>④ Monitoring and observation processes<br>⑤ Remark |
|---|---|---|
| WEL (GB)<br>from 18 Dec 2011 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (7.8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (may be absorbed through the skin) |
| IDLH (US)<br>from 1 Jan 1994 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 250 ppm |
| TRGS 900 (DE)<br>from 1 May 2010 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11 |
| ES<br>from 1 Jan 2012 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI |
| IOELV (EU)<br>from 17 Dec 2009 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (may be absorbed through the skin) |
| VRC (FR) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (7.8 mg/m³)<br>② 4 ppm (15.6 mg/m³)<br>⑤ (peut être absorbé par la peau) |
| GR<br>from 1 Oct 2016 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 2 ppm (8 mg/m³)<br>② 4 ppm (16 mg/m³)<br>⑤ (αναμένετε απορρόφηση από το δέρμα) |
| OSHA (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>⑤ (may be absorbed through the skin) |
| NIOSH (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>③ 15.6 ppm (60 mg/m³)<br>⑤ (may be absorbed through the skin) |
| ACGIH (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | ① 5 ppm (19 mg/m³)<br>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<br>② Test material<br>③ Time of sampling:<br>④ Remark |
|---|---|---|---|
| TRGS 903 (DE)<br>from 19 Sept 2013 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>Creatinin | ① Phenol<br>② Urin<br>③ Expositionsende bzw. Schichtende |
| VLB (ES)<br>from 1 Jan 2013 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>creatinina | ① fenol<br>② orina<br>③ fin de exposición o fin de turno |
| ACGIH-BEI (US) | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 250 mg/g<br>creatinine | ① phenol<br>② urine<br>③ end of exposure or end of shift |
| BLV (EU)<br>from 1 Jun 2014 | **phenol**<br>CAS No.: 108-95-2<br>EC No.: 203-632-7 | 120 mg/g<br>creatinine | ① phenol<br>② urine<br>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:** yellow
**Odour:** not determined

### Safety relevant basis data

| Parameter | Value | at °C | ① Method<br>② Remark |
|---|---|---|---|
| pH | 6.7 – 6.9 | 21 °C | |
| Melting point | *not determined* | | |
| Freezing point | *not determined* | | |
| Initial boiling point and boiling range | *not determined* | | |
| Decomposition temperature | *not determined* | | |
| Flash point | *not determined* | | |
| Evaporation rate | *not determined* | | |
| Auto-ignition temperature | *not determined* | | |
| Upper/lower flammability or explosive limits | *not determined* | | |



GeSi.de

## AESKULISA® Recovery

| Parameter | Value | at °C | ① Method<br>② Remark |
|---|---|---|---|
| Vapour pressure | *not determined* | | |
| Vapour density | *not determined* | | |
| Density | *not determined* | | |
| Relative density | *not determined* | | |
| Bulk density | *not determined* | | |
| Water solubility | *not determined* | | |
| Partition coefficient: n-octanol/water | *not determined* | | |
| Dynamic viscosity | *not determined* | | |
| Kinematic viscosity | *not determined* | | |

### 9.2. Other information
No data available

## SECTION 10: Stability and reactivity

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

### 10.2. Chemical stability
No. 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

## SECTION 11: Toxicological information

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

| **ProClin ® 300** |
|---|
| **$LD_{50}$ oral:** 862 mg/kg (Ratte) |
| **$LD_{50}$ dermal:** 2,800 mg/kg (Kaninchen) |
| **phenol** CAS No.: 108-95-2 EC No.: 203-632-7 |
| **$LD_{50}$ oral:** 317 mg/kg (Ratte) |
| **$LD_{50}$ dermal:** 630 mg/kg (Kaninchen) |

**Acute oral toxicity:**
Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**
Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**
Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**
Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**
Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**
Contains ProClin ® 300. May produce an allergic reaction.

**Germ cell mutagenicity:**
Based on available data, the classification criteria are not met.

## AESKULISA® Recovery

**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

### 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



GeSi.de

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

### Waste treatment options

**Appropriate disposal / Product:**

Consult the appropriate local waste disposal expert about waste disposal.

## SECTION 14: Transport information

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

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

No data available

### 15.2. Chemical Safety Assessment

No data available

## SECTION 16: Other information

### 16.1. Indication of changes

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




GeSi.de

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG InternationalMaritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

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

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

UN United Nations

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

## 16.3. Key literature references and sources for data
No data available

## 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]
The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

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

| **Hazard statements** | |
|---|---|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |
| H311 | Toxic in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H331 | Toxic if inhaled. |
| H341 | Suspected of causing genetic defects. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |

## 16.6. Training advice
No data available

### 16.7. Additional information

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



GeSi.de