

Safety Data Sheet

According to Regulation (EG) Nr. 1907/2006

Revision Date: 21.12.2023

Version: 003

replaced Version: 26.08.2020

AESQC® IFA Quality Controls

Product identifier

Product name:

AESQC® IFA Quality Controls

REF / Article Number	Name of product
AESQCIFANEG	AESQC® IFA Negative Control
AESQCANA01	AESQC® ANA HEp-2 Homogeneous
AESQCANA03	AESQC® ANA HEp-2 Centromere
AESQCANA04	AESQC® ANA HEp-2 Speckled
AESQCANA09	AESQC® ANA HEp-2 Nucleolar
AESQCANA21	AESQC® ANA HEp-2 Cytoplasmic
AESQCIFANAP1	AESQC® ANA HEp-2 Panel 1

Always read the intended use before using the test kit. General terms and conditions apply.

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

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Changes to the prior version:

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

Appendix

Safety Data Sheet for AESQC® IFA Quality Controls

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according to Regulation (EC) No. 1907/2006 (REACH)

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

1.1. Product identifier

Trade name/designation:

AESQC® IFA

Other means of identification:

AESQC® IFA Quality Controls

Article No.:

AESQCIFAxXX, AESQCIFANAP1, AESQCANAxX

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

Use of the substance/mixture:

AESQC® IFA Quality Controls

This Immunofluorescence assay (in-vitro diagnostic or component) is not intended to be used other than for the detection and semi quantitative determination of human IgA / IgG / IgM antibodies in autoimmune diagnostics.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

AESKU.DIAGNOSTICS GmbH & Co.KG

Mikroforum Ring 2
55234 Wendelsheim
Germany

Telephone: +49 6734 - 9622-0

Telefax: +49 6734 - 9622-2222

E-mail: info@aesku.com

Website: www.aesku.com

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

1.4. Emergency telephone number

Aesku.Diagnostics, +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

Additional information:

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.

2.3. Other hazards

Adverse physicochemical effects:

none

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Adverse human health effects and symptoms:

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
	ProClin® 300 Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317)  Danger	0 - ≤ 0.1 weight-%

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:

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

Protective equipment:

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

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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)

Industrial sector specific solutions:

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.

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

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: transparent

Odour: not determined

Safety relevant basis data

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

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

not relevant The product itself does not burn.

10.2. Chemical stability

Recommended storage temperature: 2-8°C

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

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

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

SECTION 11: Toxicological information

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

ProClin ® 300

LD₅₀ oral: 862 mg/kg (Ratte)

LD₅₀ dermal: 2,800 mg/kg (Kaninchen)

Acute oral toxicity:

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

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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

No data available

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

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

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

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

SECTION 14: Transport information

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

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

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

16.2. Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level

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EN European Standard
EWC European Waste Catalogue
IATA International Air Transport Association
ICAO International Civil Aviation Organization
IMDG International Maritime Dangerous Goods
IMO International Maritime Organization
ISO International Standards Organisation
KG body weight
LD₅₀ Lethal (fatal) Dose 50%
NFPA National Fire Protection Association
PBT persistent and bioaccumulative and toxic
PNEC Predicted No Effect Concentration
REACH Registration, Evaluation and Authorization of Chemicals
RID Dangerous goods regulations for transport by rail
UN United Nations
°C centigrade
CO carbon monoxide
CO₂ carbon dioxide
IVD in vitro diagnostics
MARPOL International Convention for the Prevention of Marine Pollution
NIOSH National Institute for Occupational Safety and Health
vPvB very Persistent (vP), very Bioaccumulative (vB)

16.3. Key literature references and sources for data

No data available

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

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

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

Hazard statements	
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.