

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1. Product identifier**

Product Description: Quality Club ECP
Cat No. : 10-9344-01

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

Recommended Use In vitro diagnostic
Uses advised against All other uses

1.3. Details of the supplier of the safety data sheet

Company Phadia AB
Rapsgatan 7P
P.O. Box 6460
751 37 UPPSALA
Sweden
+46 18 16 50 00
E-mail address safetydatasheet.idd@thermofisher.com

1.4. Emergency telephone number

CHEMTREC Ireland (Dublin) +(353)-19014670
CHEMTREC Belgium (Brussels) +(32)-28083237
Malta 112 Emergency phone number

SECTION 2: HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture****GHS Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567****Physical hazards**

Based on available data, the classification criteria are not met

Health hazards

Based on available data, the classification criteria are not met

Environmental hazards

Based on available data, the classification criteria are not met

For the full text of the H-statements mentioned in this Section, see Section 16.

2.2. Label elements

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

2.3. Other hazards

This product contains human sourced material. The donors have been tested and found to be non-reactive for HBsAg, HIV-1 Ag, anti-HCV and anti HIV-1/HIV-2. This product does not contain any known or suspected endocrine disruptors. This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

3.2. Mixtures

Component	CAS No	EC No	Weight %	GHS Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Pooled human sera	-		100	-

For the full text of the H-statements mentioned in this Section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Eye Contact	Rinse thoroughly with plenty of water, also under the eyelids.
Skin Contact	Wash off immediately with soap and plenty of water.
Ingestion	Rinse mouth. If possible drink milk afterwards.
Inhalation	Not applicable.
Self-Protection of the First Aider	Not Applicable.

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

No information available.

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

Notes to Physician	Treat symptomatically.
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SECTION 5: FIREFIGHTING MEASURES

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

5.1. Extinguishing media

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which must not be used for safety reasons

None known.

5.2. Special hazards arising from the substance or mixture

None known.

Hazardous Combustion Products

None known.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear protective gloves/clothing and eye/face protection.

6.2. Environmental precautions

Dispose of in accordance with local regulations.

6.3. Methods and material for containment and cleaning up

Wipe up with adsorbent material (e.g. cloth, fleece). Dispose of waste product or used containers according to local regulations.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Keep at temperatures between 2 and 8°C.

7.3. Specific end use(s)

Observe instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

Derived Minimum Effect Level (DMEL) / Derived No Effect Level (DNEL)

No information available

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

None under normal use conditions.

Personal protective equipment

Eye Protection

No special protective equipment required.

Hand Protection

Protective gloves.

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers recommendations	-	EN 374	(minimum requirement)

Skin and body protection

No special protective equipment required.

Respiratory Protection

No protective equipment is needed under normal use conditions.

Large scale/emergency use

No protective equipment is needed under normal use conditions

Small scale/Laboratory use

No personal respiratory protective equipment normally required.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

Environmental exposure controls Dispose of contents/containers in accordance with local regulations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State	Liquid	
Appearance	Colorless to yellow	
Odor	None	
Odor Threshold	None	
Melting Point/Range	No data available	
Softening Point	No data available	
Boiling Point/Range	No data available	
Flammability (liquid)	No data available	
Flammability (solid,gas)	Not flammable	
Explosion Limits	Not applicable	
Flash Point	Not applicable	Method - No information available
Autoignition Temperature	Not applicable	
Decomposition Temperature	Not applicable	
pH	No data available	
Viscosity	No data available	
Water Solubility	Soluble in water	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	No data available	
Vapor Density	No data available	(Air = 1.0)
Particle characteristics	Not applicable (liquid)	

9.2. Other information

Explosive Properties	Not applicable
Oxidizing Properties	Not applicable

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions	None under normal processing.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

None known.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Product Information Product does not present an acute toxicity hazard based on known or supplied information.

(a) acute toxicity;

Oral

No data available.

Dermal

No data available.

Inhalation

No data available.

Toxicology data for the components

(b) skin corrosion/irritation; No data available.

(c) serious eye damage/irritation;

(d) respiratory or skin sensitization;

Respiratory

No data available.

Skin

No data available.

(e) germ cell mutagenicity; No data available.

(f) carcinogenicity; There are no known carcinogenic chemicals in this product.

(g) reproductive toxicity; No data available.

(h) STOT-single exposure; No data available.

(i) STOT-repeated exposure; No data available.

(j) aspiration hazard; No data available.

Symptoms / effects, both acute and delayed No information available.

11.2. Information on other hazards

Endocrine Disrupting Properties This product does not contain any known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity effects No information available.

12.2. Persistence and degradability No information available.

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

<u>12.3. Bioaccumulative potential</u>	No information available.
<u>12.4. Mobility in soil</u>	No information available.
<u>12.5. Results of PBT and vPvB assessment</u>	This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB).
<u>12.6. Endocrine disrupting properties</u> Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors
<u>12.7. Other adverse effects</u> Persistent Organic Pollutant Ozone Depletion Potential	No known effect. No known effect.

SECTION 13: DISPOSAL CONSIDERATIONS

<u>13.1. Waste treatment methods</u>	
Waste from Residues/Unused Products	Dispose of in accordance with local regulations.
Contaminated Packaging	Dispose of in accordance with local regulations.
European Waste Catalogue (EWC) Other Information	18 01 07 Chemicals other than those mentioned in 18 01 06. No information available.

SECTION 14: TRANSPORT INFORMATION

<u>IMDG/IMO</u>	Not regulated
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> <u>14.3. Transport hazard class(es)</u> <u>14.4. Packing group</u>	
<u>ADR</u>	Not regulated
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> <u>14.3. Transport hazard class(es)</u> <u>14.4. Packing group</u>	
<u>IATA</u>	Not regulated
<u>14.1. UN number</u> <u>14.2. UN proper shipping name</u> <u>14.3. Transport hazard class(es)</u> <u>14.4. Packing group</u>	
<u>14.5. Environmental hazards</u>	No hazards identified.
<u>14.6. Special precautions for user</u>	No special precautions required.

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods.

SECTION 15: REGULATORY INFORMATION

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

International Inventories

X = listed

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) is not required.

SECTION 16: OTHER INFORMATION

Legend

CAS - Chemical Abstracts Service

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

ENCS - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

ACGIH - American Conference of Governmental Industrial Hygienists

DNEL - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

Key literature references and sources for data

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

ATE - Acute Toxicity Estimate

VOC (volatile organic compound)

Physical hazards

On basis of test data

Health Hazards

Calculation method

Environmental hazards

Calculation method

Training Advice

SAFETY DATA SHEET

Quality Club ECP

Revision Date 03-Jan-2024

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Revision Date 03-Jan-2024

Revision Summary SDS sections updated, 7.

This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet