EU Ecolabel for Reusable Menstrual Cups

User Manual

Version 1, July 2023

European Commission

EU Ecolabel for Reusable Menstrual Cups

Contents

Using this manual

This manual guides you through the process of applying for an EU Ecolabel, in accordance with the criteria requirements. The following symbols are used throughout:

Symbol description	
	Boxes with definitions or additional explanations of technical terms that could complement the definitions already included in Commission Decision (EU) 2023/1809[1].
	Notable or important information.
	Documentation on how to fill in the application form and information about documents to be submitted with the application.
	Website links where further information can be found.

The manual is structured as follows:

Part A: General Information – provides information about the EU Ecolabel, details of the application process as well as frequently asked questions about the applications.

Part B: Product Assessment and Verification – outlines the criteria for the specific product group set out in the Commission Decision.

The manual is supplemented by the following elements as separate files:

- Application Form: a spreadsheet to be filled in.
- Declarations: as editable pdf files to be filled in.

The spreadsheet contains a first tab labelled "Read_me", which contains the information needed for the application form, data submission and declarations. Additionally, there are dedicated tabs for each criterion. The last tab in all spreadsheets is named "Data_summary" and it gathers anonymous information submitted in previous tabs of the Application Form.

The applicant may gather all the declarations from their suppliers and provide them to the assessing competent body together with the application form. Alternatively, these declarations can also be provided directly by the supplier to the competent body.

⚠ *Please read this manual all the way through before completing and submitting the verification form or any other documentation. EU Ecolabel competent bodies can help applicants/licence holders understand the EU Ecolabel criteria and can provide guidance on how to assemble an application dossier.*

All referenced legal acts are available at: https://eur-lex.europa.eu/homepage.html

[1] Commission Decision (EU) 2023/1809 of 14 September 2023 establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups (OJ L 234, 22.9.2023, p. 142)

⚠ *This User Manual is for guidance only; it does not have any legal standing and does not, in any way, replace the Commission Decision or any relevant legislation. In case of doubt on specific points in the Manual, please refer directly your national Competent Body.*

1 Introduction

This User Manual is for guidance only and is designed to support the application phase for the EU Ecolabel for reusable menstrual cups (RMC). It includes an outline of all data, tests and documentation that are required to demonstrate compliance with the criteria.

The basis for the manual is the Commission Decision (EU) 2023/1809 establishing the EU Ecolabel criteria for reusable menstrual cups. A copy of the criteria can be found at:

- http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html

This document does not aim to duplicate the content of the criteria but is intended to support their interpretation, and is only focused on helpful explanations and clarifications. Each criterion name appears as a heading under Part B with a short summary of what documents are needed for the verification of the criterion. The exact criterion text does not appear in this User Manual. Only additional information, clarifications and explanations are included.

⚠ *Please read Commission Decision (EU) 2023/1809 establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups and this manual all the way through before completing and submitting the application form or any other documentation.*

For general questions about the EU Ecolabel and the application process please check the following pages:

- http://ec.europa.eu/environment/ecolabel/faq.html
- http://ec.europa.eu/environment/ecolabel/how-to-apply-for-eu-ecolabel.html

2 Before you start

We recommend that before you start you take the following steps:

⚠ *Read Commission Decision (EU) 2023/1809 and its Annex carefully*[2].

⚠ *Contact the competent body of your choice*[3].

⚠ *Make sure that the candidate product fulfils all applicable legal requirements of the country or countries in which the product is intended to be placed on the market.*

[2] Commission Decision (EU) 2023/1809 of 14 September 2023 establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups (OJ L 234, 22.9.2023, p. 142)

[3] More information of your competent body is available at https://ec.europa.eu/environment/ecolabel/competent-bodies.html

3 Part A: General Information

Part A 'General information' is a horizontal document for all EU Ecolabel products, explaining the different steps of the application process in detail. It has been translated into each Member State language and can be found at:

- https://environment.ec.europa.eu/publications/eu-ecolabel-translated-user-manuals-part_en

4 Part B: Product Assessment and Verification

4.1 Scope

The scope of the product group "reusable menstrual cups" (RMC) is reported in Article 2 of Commission Decision (EU) 2023/1809 and is as follows:

> *The product group 'reusable menstrual cups' shall comprise reusable flexible cups or barriers worn inside the body whose function is to retain and collect menstrual fluid, and made of silicone or other elastomers.*

Products falling under the scope of Regulation (EU) 2017/745[4] are excluded from the scope of this EU Ecolabel.

> ⚠ *Reusable menstrual cups can be eligible for the EU Ecolabel only if such products are not registered as medical devices under the Medical Devices Regulation (EU) 2017/745. The applicant is requested to state in the Application Form that the reusable menstrual cups has not been registered as medical device.*

[4] Regulation (EU) 2017/745 on medical devices (OJ L 117, 5.5.2017, p. 1).

4.2 Definitions for Reusable Menstrual Cups

The following definitions shall apply to references throughout this User Manual for RMC, and in reference to the original criteria document:

(1) 'additives' means substances added to components, materials or the final product in order to improve or preserve some of its characteristics;

(2) 'composite packaging' means a unit of packaging made of two or more different materials, excluding materials used for labels, closures and sealing, which cannot be separated manually and therefore form a single integral unit;

(3) 'grouped packaging', also known as secondary packaging, means packaging conceived so as to constitute a grouping of a certain number of sales units at the point of sale whether the latter is sold as such to the end user or it serves only as a means to replenish the shelves at the point of sale or create a stock-keeping or distribution unit, and which can be removed from the product without affecting its characteristics;

(4) 'impurities' means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the raw material/ingredient and/or in the chemical product (used in the final product and any component therein) in concentrations less than 100 ppm (0,0100 % w/w, 100 mg/kg);

> ⚠ *Examples of impurities are residues of the following: residues or reagents including residues of monomers, catalysts, by-products and detergents for production equipment and carry-over from other or previous production lines.*

(5) 'ingoing substance' means all substances included in the chemical product (used in the final product and any component therein), including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances in stabilized manufacturing conditions (e.g. formaldehyde and arylamine) are also considered as ingoing substances;

(6) 'packaging' means items of any materials that are intended to be used for the containment, protection, handling, delivery or presentation of products and that can be differentiated into packaging formats based on their function, material and design, including:

> (a) items that are necessary to contain, support or preserve the product throughout its lifetime without being an integral part of the product which is intended to be used, consumed or disposed of together with the product;
>
> (b) components of, and ancillary elements to, an item referred to in point (a) that are integrated into the item;
>
> (c) ancillary elements to an item referred to in point (a) that are hung directly on, or attached to, the product and that perform a packaging function without being an integral part of the product which is intended to be used, consumed or disposed of together with the product; etc;

(7) 'plastic materials', also referred to as 'plastics', means polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, to which additives or other substances may have been added, and which are capable of functioning as main structural components of final products and/or packaging, with the exception of natural polymers that have not been chemically modified;

(8) 'polymer' means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition, a 'monomer unit' means the reacted form of a monomer substance in a polymer, as defined in Regulation (EC)

No 1907/2006;

(9) 'recyclability' means the amount (mass or percentage) of an item available for recycling;

(10) 'recycled content' means the amount of an item (by area, length, volume or mass) that is sourced from post-consumer and/or post-industrial recycled material. Item can refer to the product or to the packaging in this case;

(11) 'recycling' means, in accordance with Article 3 of Directive 2008/98/EC of the European Parliament and of the Council , any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations;

(12) 'sales packaging', also known as primary packaging, means packaging conceived so as to constitute a sales unit consisting of products and packaging to the final user or consumer at the point of sale;

(13) 'separate component', also known as additional component, means a packaging component that is distinct from the main body of the packaging unit, which may be of a different material, that needs to be disassembled completely and permanently from the main packaging unit in order to access the product, and that is typically discarded prior to and separately from the packaging unit. In the case of absorbent hygiene products, it is any component with protective or hygienic function that is removed before the use of the product, e.g. the individual wrapping or film where some absorbent hygiene products are contained within the sales packaging (mainly for tampons and sanitary pads), the release liner and paper in baby diapers and sanitary pads, or the applicator for tampons;

(14) 'substances identified to have endocrine disrupting properties', also referred to as endocrine disruptors, means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 (candidate list of substances of very high concern for authorisation), or Regulation (EU) No 528/2012 of the European Parliament and of the Council or Regulation (EC) No 1107/2009 of the European Parliament and of the Council , or Regulation (EC) No 1272/2008 of the European Parliament and of the Council ;

(15) 'synthetic polymers' means macromolecular substances other than cellulose pulp intentionally obtained either by:

(a) a polymerisation process such as poly-addition or poly-condensation or by any other similar process of combination of monomers and other starting substances;

(b) chemical modification of natural or synthetic macromolecules;

(c) microbial fermentation.

4.3 Assessment and verification of the criteria

For the EU Ecolabel to be awarded to a specific product, the product shall comply with each requirement. The applicant shall provide a written confirmation stating that all the criteria are fulfilled.

Specific assessment and verification requirements are indicated within each criterion.

> Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s) as appropriate.

Competent bodies shall preferentially recognise attestations that are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories, and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes, and services.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been awarded shall be notified to competent bodies, together with supporting information to enable verification of continued compliance with the criteria.

As pre-requisite, the product shall meet all respective legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

The following information shall be provided together with the application for the EU Ecolabel:

(a) a description of the product, together with the weight of the individual product units and the total weight of the product;

(b) a description of the sales packaging, together with its total weight, if applicable;

(c) a description of the grouped packaging, together with its total weight, if applicable;

(d) a description of the separate components, together with their individual weight;

(e) the components, materials and all substances used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

4.4 Product group criteria

Table: EU Ecolabel criteria for RMC

No.	Criterion
1	Emissions during production of the raw material
1.1	Emissions of dust and chlorides to air
1.2	Emissions of copper and of zinc to water
1.3	Emissions of CO_2
2	Environmental management of production
3	Material efficiency in the manufacturing of the final product
4	Excluded and restricted substances
4.1	Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council
4.2	Substances of Very High Concern (SVHCs)
4.3	Other specific restrictions
5	Packaging
6	Guidance on the disposal of the product and of the packaging
7	Information for the user
8	Fitness for use and quality of the product
9	Corporate Social Responsibility with regard to Labour Aspects
10	Information appearing on the EU Ecolabel

Criterion 1: Emissions during production of the raw material

Criterion 1 focuses on the sourcing and production of the raw material for the production of the reusable menstrual cups (RMC), and lays down requirement for RMC made of silicone or other elastomers such as thermoplastic elastomers (TPE).

This criterion is sub-divided into three sub-criteria which focus on:

- Emissions to air;
- Emissions to water;
- CO_2 emissions.

1.1 Emissions of dust and of chlorides to air

Emissions of dust

⚠ *The following requirements apply to silicone cups only*

The storage and handling of elemental silicon shall use at least one of the following techniques:

- Storing of elemental silicon in silos (after grinding);
- Storing of elemental silicon in covered areas protected from rain and wind (after grinding);
- Using equipment designed with hooding and ducting to capture diffuse dust emissions during the loading of elemental silicon into storage (after grinding);
- Maintaining the atmosphere of the grinder at a slightly lower pressure than atmospheric pressure.

⚠ *The following requirement applies to both silicone and other elastomers*

Emissions of dust shall be below 5 mg/Nm^3.

The emissions should be expressed as yearly average of channelled emissions of dust.

Methods accepted are:

- EN 15267-1:2009 Air quality - Certification of automated measuring systems - Part 1: General principles)
- EN 15267-2:2009 Air quality - Certification of automated measuring systems - Part 2: Initial assessment of the AMS manufacturer's quality management system and post certification surveillance for the manufacturing process
- EN 15267-3:2008 Air quality - Certification of automated measuring systems - Part 3: Performance criteria and test procedures for automated measuring systems for monitoring emissions from stationary sources
- EN 15267-4:2017 Air quality - Certification of automated measuring systems - Part 4: Performance criteria and test procedures for automated measuring systems for periodic measurements of emissions from stationary sources
- EN 13284-1:2017 Stationary source emissions - Determination of low range mass concentration of dust - Part 1: Manual gravimetric method

- EN 13284-2:2017 Stationary source emissions - Determination of low range mass concentration of dust - Part 2: Quality assurance of automated measuring systems.

The dust emissions should be continuously monitored.

⚠ *For silicone cups, the measurement shall cover grinding, storage and handling of elemental silicon as a minimum*

Emissions of chlorides

⚠ *The following requirements apply to silicone cups only*

The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. Burning of chlorinated compounds shall be authorised in the thermal oxidation process.

Emission of chlorides during silicone production

During silicone material production, chlorides emissions occur during the methyl chloride synthesis, the direct synthesis and the distillation process steps. The off-gases from the methyl chloride synthesis mainly consists of nitrogen (87 – 89 %), dimethylether (10 %), methyl chloride (1 – 3 %), methanol and traces of hydrocarbons. The off-gases from the direct synthesis step mainly consists of nitrogen (70 – 80 %), methane (10 – 20 %), hydrogen (5 %), hydrocarbon (1 – 2 %) and methyl chloride (1 %). Finally, the off-gases from the distillation step contains nitrogen, methyl chloride and methylchlorosilane.

Given the presence of light hydrocarbons and chlorinated compounds, the off gases from these steps must undergo a thermal oxidation step to minimize the risk of polychlorinated dibenzodioxins/furans (PCDD/F) formation. In addition, some plants apply a 'fast-quench' of post-combustion gases by cooling them very quickly from high temperatures to below the temperature-window of dioxins/furans reformation.

⚠ *The following requirement applies to both silicone and other elastomers*

Emissions of polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDF) shall be below 0.01 ng TEQ/Nm^3.

The emissions should be expressed as average over the sampling period.

Methods accepted are: EN 1948-1, EN 1948-2 and EN 1948-3.

Monitoring of the PCDD/F emissions should take place every six months.

Required documentation:

- Declaration of compliance from the raw material supplier (template available separately)
- In the case of silicone cups, information on which silicon storage and handling technique is used on site, providing pictures or technical descriptions as supplementary data
- Results of the dust measurements taken on site as well as the yearly average of the dust emission
- In the case of silicone cups, information on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps
- In the case of elastomers other than silicone, results of the PCDD/F emissions measurements of the treated gases

1.2 Emissions of copper and of zinc to water

This sub-criterion applies to silicones only.

The water effluents from the polydimethylsiloxane (PDMS) production step shall be pre-treated by precipitation or flocculation under alkaline conditions, followed by sedimentation and filtration. This includes:

(a) dewatering of the sludge before disposal; and

(b) recovering of the solid metal residues in metal recovery plants.

Emissions of copper in the treated effluent shall be below 0.5 mg/l

Emissions of zinc in the treated effluent shall be below 2 mg/l.

Required documentation:

- Declaration of compliance from the silicone supplier (template available separately)
- Written documentation that the production plant has in place a wastewater system consisting of a precipitation/flocculation step followed by a sedimentation step
- Measurement results for copper and zinc in the treated effluent

1.3 Emissions of CO_2

⚠ *The following requirements apply to silicone only*

CO_2 emissions from the production of silicone shall not exceed 6.58 kg per kg silicone.

The calculation of CO_2 emissions shall include all sources of energy used during the production of silicone, and shall include also the emissions from the production of electricity (whether on-site or off-site).

For the calculation of CO_2 emission from fuels and electricity, the reference emission values according to Table 1 of Annex II to Commission Decision (EU) 2023/1809 (also reported below) shall be used.

⚠ *If needed, CO2 emission factors for energy sources other than those listed in* Table *1 can be found in Annex VI to Regulation (EU) 2018/2066*

⚠ *For the grid electricity, it is possible to use a specific value for the electricity used instead of the one reported in* Table *1, but appropriate documentation shall be provided (e.g. copy of a contract)*

Table 1: Reference values for CO_2 emissions from different energy sources

Fuel	CO_2 emissions	Unit
Coal	94.6	g CO_2 fossil/MJ
Crude oil	73.3	g CO_2 fossil/MJ
Fuel oil 1	74.1	g CO_2 fossil/MJ
Fuel oil 2-5	77.4	g CO_2 fossil/MJ
LPG	63.1	g CO_2 fossil/MJ
Natural Gas	56.1	g CO_2 fossil/MJ
Grid Electricity	376	g CO_2 fossil/kWh

Renewable energy

'Energy from renewable sources', or 'renewable energy', is defined as in Directive (EU) 2018/2001 on the promotion of the use of energy from renewable sources as: "energy from renewable non-fossil sources, namely wind, solar (solar thermal and solar photovoltaic) and geothermal energy, ambient energy, tide, wave and other ocean energy, hydropower, biomass, landfill gas, sewage treatment plant gas, and biogas".

Energy from renewable sources count as zero CO_2 emissions for all the above except for biomass energy.

For biomass energy to be counted as zero CO_2 emissions, the biomass needs to fulfil the relevant sustainability and greenhouse gas savings criteria as specified in Article 29 of Directive (EU) 2018/2001.

The measurement period shall be of 12 months of production. The measurement shall be representative of the respective campaign.

For a new or re-built plant or a change of process at the production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant.

⚠ *Results shall be repeated and shown on a yearly basis.*

Required documentation:

- Declaration of compliance with the sub-criterion from the supplier(s) (template available separately)
- Data and detailed calculations on the CO_2 emissions showing compliance with this requirement, together with related supporting documentation. An excel tab is available in the electronic Application Form.
- If renewable energy is used, documentation shall be provided that renewable energy is actually used at the plant or that it has been externally purchased (e.g. copy of an energy contract).
- If a different reference value for electricity is used instead of the one reported in Table 1, documentation shall be provided that include technical specifications that indicate the average value for the electricity used (e.g. copy of a contract).

Criterion 2: Environmental management of production

The aim of this criterion is to set a series of additional measures in line with the reduction of the environmental impact of the manufacturing of raw materials (silicone or other elastomers) and of the cups themselves.

⚠ *In this criterion, it is required that manufacturers of silicone or other elastomers and RMC manufacturing sites implement systems for:*

- *water-saving,*
- *integrated waste management plan,*
- *optimisation of energy efficiency and energy management.*

(a) water-savings. The water management system shall be documented or explained and shall include information on at least the following aspects: monitoring of water flows; proof of circulating water in closed systems; and continuous improvement objectives and targets relating to the reduction of wastewater generation and optimisation rates (if relevant, i.e. if water is used in the plant);

(b) integrated waste management, in form of a plan to prioritise treatment options other than disposal for all the waste generated at the manufacturing facilities and to follow the waste hierarchy in relation to prevention, reuse, recycling, recovery and final disposal of waste. The waste management plan shall be documented or explained and shall include information on at least the following aspects: separation of different waste fractions; handling, collection, separation and use of recyclable materials from the non-hazardous waste stream; recovery of materials for other uses; handling, collection, separation and disposal of hazardous waste, as defined by the relevant local and national regulatory authorities; and continuous improvement objectives and targets relating to waste prevention, reuse, recycling and, recovery of waste fractions that cannot be prevented (including energy recovery);

(c) optimisation of energy efficiency and energy management. The energy management system shall address all energy consuming devices, including machinery, lighting, air conditioning and cooling. The energy management system shall include measures for the improvement of energy efficiency and shall include information on at least the following aspects: establishing and implementing an energy data collection plan in order to identify key energy figures; analysis of energy consumption that includes a list of energy consuming systems, processes and facilities; identification of measures for more efficient use of energy; continuous improvement objectives and targets relating to the reduction of energy consumption.

⚠ *Applicants registered with EU Eco-Management and Audit Scheme (EMAS) and/or certified according to ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme shall be considered as having fulfilled these requirements if:*

⚠ *(a) the inclusion of water, waste and energy management plans for the production site(s) of RMC and raw materials (silicone or other elastomers) is documented in the company's EMAS environmental statement; or*

⚠ *(b) the inclusion of water, waste and energy management plans for the production site(s) of RMC and raw materials (silicone or other elastomers) is sufficiently addressed by the ISO 14001, ISO 50001, EN 16247 or an equivalent standard/scheme*

Required documentation:

- Declaration of compliance with the criterion from the manufacturers of RMC and of the raw materials (silicone or other elastomers) (template available)
- Report describing in detail the procedures adopted by the manufacturers of RMC and raw materials (silicone or other elastomers) in order to fulfil the requirements for each of the sites concerned in accordance with standards, such as ISO 14001 and/ or ISO 50001 for water, waste and energy plans
- If waste management is outsourced, the sub-contractor shall provide a declaration of compliance with this criterion as well

Criterion 3: Material efficiency in the manufacturing of the final product

This criterion aims to limiting the amount of waste that is sent to landfill or incineration in the final product manufacturing site. The waste recovered for reuse, recycling or energy production is not targeted by this criterion.

⚠ *Requirements in this criterion shall apply to the final product manufacturing site.*

The quantity of waste generated during the manufacturing and packaging of the end products which is sent to landfill or incineration without energy recovery, shall not exceed:

⚠ *4 % by weight of the end products.*

Information to be included in the declaration of compliance with this criterion relates to the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy.
The applicant shall present all of the following:

- Weight of the product and of the packaging
- All waste streams generated during the manufacture,
- Respective treatment processing of the fraction of recovered waste and that disposed of to landfill or incineration.

⚠ *The quantity of waste sent to landfill or to incineration without energy recovery shall be calculated as the difference between the amount of waste produced and the amount of waste recovered (reused, recycled, etc).*

Interpretation of criterion

- The total quantity of waste generated during manufacturing and packaging of the end product must be reported indicating how different fractions are handled, treated and, if it is the case, reused or recovered.
- Fractions of waste that are reused or converted into useful materials and/or energy shall be subtracted from the total.
- Treatment processes not providing added value in terms of materials and/or energy recovery (e.g. incineration without energy recovery) shall not be subtracted from the total.

Required documentation:

Declaration of compliance with the criterion (template available).

Criterion 4: Excluded and restricted substances

4.1 Restrictions on substances classified under Regulation (EC) No 1272/2008

This sub-criterion applies to ingoing substances added to the chemical product used in the final product and in any component of it.

This sub-criterion covers restricted and excluded substances under Regulation (EC) No 1272/2008.

This criterion does not apply to:

- substances not included in the scope of Regulation (EC) No 1907/2006 as defined in Article 2(2) of that Regulation;
- substances covered by Article 2(7)(b) of Regulation (EC) No 1907/2006, which sets out the criteria for exempting substances included in Annex V to that Regulation from the registration, downstream user and evaluation requirements.

Excluded substances

The final product and any components therein shall not contain ingoing substances (added as such or in mixtures) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 2 in Annex II to Commission Decision (EU) 2023/1809 (and also reported below).

⚠ *Such ingoing substances shall thus not be intentionally added to the chemical product used in the final product*

⚠ *Classified substances according to Table 2 in Annex II to Commission Decision (EU) 2023/1809 can only occur as impurities in the raw material, and always in a concentration lower than 0.0100% w/w of the chemical product that is added to the final product*

⚠ *Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities and shall comply with this requirement*

Table 2 Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	Category 2
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	-
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child

H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	
Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target organ toxicity	
Category 1	Category 2
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1A	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Endocrine disruptors for human health and the environment	
Category 1	Category 2
EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
EUH430: May cause endocrine disruption in the environment	EUH431: Suspected of causing endocrine disruption in the environment
Persistent, Bioaccumulative and Toxic	
PBT	vPvB
EUH440: Accumulates in the environment and living organisms including in humans	EUH441: Strongly accumulates in the environment and living organisms including in humans
Persistent, Mobile and Toxic	
PMT	vPvM

EUH450: Can cause long-lasting and diffuse contamination of water resources	EUH451: Can cause very long-lasting and diffuse contamination of water resource

The hazard statement codes generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

The most recent classification rules adopted by the Union shall take precedence over the listed hazard classifications. Applicants shall therefore ensure that any classifications are based on the most recent classification rules.

For classified impurities, the applicant (or the supplier) shall use the concentration of the restricted impurity and an assumed retention factor of 100% in order to estimate the quantity of the impurity remaining in the chemical product.

The use of substances or mixtures that are chemically modified during the production process, so that any relevant hazard for which the substance or mixture has been classified under Regulation (EC) No 1272/2008 no longer applies, shall be exempted from the above requirement. This includes, for example, modified polymers and monomers or additives which become covalently bonded within plastics.

⚠ *Justifications for any deviation from a retention factor of 100% (e.g. solvent evaporation) or for chemical modification of a restricted impurity shall be provided.*

Restricted substances

The final product and any components therein shall not contain ingoing substances (added as such or in mixtures) in concentrations greater than 0,010% (weight by weight) in the chemical product that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 3 in Annex II to Commission Decision (EU) 2023/1809 (and also reported below).

⚠ *The concentration of such ingoing substances shall be calculated with respect to the chemical product that is added to the final product*

⚠ *Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities and shall comply with this requirement*

Table 3 Restricted hazard classes, categories and associated hazard statement codes

Hazardous to the aquatic environment	
Categories 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	
Hazardous to the ozone layer	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	-

The hazard statement codes generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

The most recent classification rules adopted by the Union shall take precedence over the listed hazard classifications. Applicants shall therefore ensure that any classifications are based on the most recent classification rules.

For substances with a restricted classification, the applicant (or the supplier) shall use the concentration of the restricted substance and an assumed retention factor of 100% in order to estimate the quantity remaining in the chemical product.

The use of substances or mixtures that are chemically modified during the production process, so that any relevant hazard for which the substance or mixture has been classified under Regulation (EC) No 1272/2008 no longer applies, shall be exempted from the above requirement. This includes, for example, modified polymers and monomers or additives which become covalently bonded within plastics.

⚠ *Justifications for any deviation from a retention factor of 100% (e.g. solvent evaporation) or for chemical modification of a restricted substance shall be provided.*

Derogated substances

Substances with an excluded or restricted hazard class that are derogated from criterion 7.1 are listed in Table 4 of Annex II to Commission Decision (EU) 2023/1809 (and also reported below).

Table 4 Derogated substances and derogation conditions

Substance type	Derogated hazard classes	Derogation conditions
H304 substances and mixtures	H304	Substances with a viscosity under 20.5 cSt at 40°C.
Titanium dioxide (nano form)	H351	Only when used as pigment. It cannot be used in powder or spray form.

Required documentation:

- Declaration of compliance with this sub-criterion (template available separately)
- A list of all substances and mixtures used in the chemical products added to the final product, as well as their concentration. A template is available as part of the electronic Application Form.

⚠ *The information provided shall relate to the forms or physical states of the substances or mixtures as used in the final product.*

- Safety Data Sheets or chemical supplier declarations of all substances used in the chemical products added to the final product.
- In case of deviation from a retention factor of 100% for a substance, written justification shall be provided

For substances exempted from sub-criterion 4.1 (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration by the applicant shall be provided

The following technical information shall be provided to support the declaration of classification or non-classification for each substance and mixture:

- for substances that have not been registered under Regulation (EC) No 1907/2006 or which do not yet have a harmonised CLP classification: information meeting the requirements listed in Annex VII to that Regulation;
- for substances that have been registered under Regulation (EC) No 1907/2006 and which do not meet the requirements for CLP classification: information based on the REACH registration dossier confirming the non-classified status of the substance;
- for substances that have a harmonised classification or are self-classified: safety data sheets where available. If these are not available or the substance is self-classified then information shall be provided relevant to the substance's hazard classification in accordance with Annex II to Regulation (EC) No 1907/2006;
- in the case of mixtures: safety data sheets where available. If these are not available then calculation of the mixture classification shall be provided according to the rules under Regulation (EC) No 1272/2008 together with information relevant to the mixtures hazard classification in accordance with Annex II to Regulation (EC) No 1907/2006.

4.2 Substances of Very High Concern (SVHCs)

This sub-criterion applies to ingoing substances added to the chemical product used in the final product and in any component of it.

The final product and any components therein shall not contain ingoing substances (added as such or in mixtures) that meet the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list for substances of very high concern for authorisation

- ⚠ *SVHCs shall thus not be intentionally added to the chemical product used in the final product*
- ⚠ *SVHCs can only occur as impurities in the raw material, and always in a concentration lower than 0.0100% w/w of the chemical product that is added to the final product*
- ⚠ *Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities and shall comply with this requirement*

As the SVHCs list is dynamic and in continuous update, attention should be paid to check the latest list available on the submission date of the EU Ecolabel application.

- The latest list can always be found at:
  http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

For SVHCs occurring as impurities, the applicant (or the supplier) shall use the concentration of the impurity and an assumed retention factor of 100% in order to estimate the quantity of the impurity remaining in the chemical product.

The use of substances or mixtures that are chemically modified during the production process, so that any relevant hazard for which the substance or mixture has been classified under Regulation (EC) No 1272/2008 no longer applies, shall be exempted from the above requirement. This includes, for example, modified polymers and monomers or additives which become covalently bonded within plastics.

- ⚠ *Justifications for any deviation from a retention factor of 100% (e.g. solvent evaporation) shall be provided.*

Required documentation:

- Declaration of compliance with this sub-criterion (template available separately)
- A list of all known SVHC impurities in the chemical products added to the final product, as well as their concentration. A template is available as part of the electronic Application Form.
- Safety Data Sheets or chemical supplier declarations of all SVHC impurities occurring in the chemical product added to the final product.
- In case of deviation from a retention factor of 100% for a SVHC impurity, written justification shall be provided

4.3 Other specific restrictions

4.3.1 Specified excluded substances

This sub-criterion applies to ingoing substances added to the chemical product used in the final product and in any component of it.

The following substances shall not be added (alone or in mixtures) to the final product, nor in any components therein

- ⚠ *The substances listed in this sub-criterion are thus only allowed as impurities, and nevertheless in concentrations lower than 0.0100% w/w in the chemical product*
- ⚠ *Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities.*

- 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT)
- Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives
  - ⚠ *Sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole are allowed*
  - Substance name = "Alkyl phenol", under: https://echa.europa.eu/es/advanced-search-for-chemicals
- Antibacterial agents (e.g. Nanosilver and triclosan)
  - ⚠ *Antibacterial agent are chemicals/products that inhibit or stop growth of microorganisms such as bacteria, fungi or protozoa (single-celled organisms)*
- Formaldehyde and formaldehyde releasers
  - ⚠ *The use of formaldehyde and formaldehyde releasers in adhesives is regulated according to sub-criterion 7.3.5*
- Methylisothiazolinone (MIT)
- Nitromusks and Polycyclic musks
- Organotin compounds used as a catalysts in the production of silicone
- Parabens
- Phthalates
- Substances identified to have endocrine disrupting properties

Substances identified to have endocrine disrupting properties means substances which have been identified to have endocrine disrupting properties (human health and or/environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (candidate list of substances of very high concern for authorisation) or according to Regulations (EU) No 528/2012 or (EC) No 1107/2009 of the European Parliament and of the Council.

⚠ *The National Authorities List I can be consulted, as it includes the substances that have undergone an evaluation of endocrine disrupting properties, as regulated in the EU in PPPR, BPR or REACH, and which are identified as endocrine disruptors*

- https://edlists.org/

⚠ *It is recommended to check the national authority list to have an overview of all identified endocrine disrupting substances evaluated in the context of different EU Regulations (list I).*

⚠ *It is advised to avoid as far as possible the substances in the list II (substances under evaluation for endocrine disruption under an EU legislation), as these are likely to be banned in future EU Ecolabel criteria revisions and/or EU Regulations.*

- Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects.
  - The list of such substances can be found in Annex 13, retrievable at this link: https://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm

Required documentation:

- Declaration of compliance with this sub-criterion (template available separately)
- Chemical supplier declarations, if relevant

4.3.2 Fragrances

Fragrances shall not be added to the final product, to any component of it, to the separate components nor to the packaging.

Required documentation:

- Declaration of compliance with this sub-criterion (template available separately)
- Chemical supplier declarations, if relevant

4.3.3 Inks and dyes

This sub-criterion applies to the final product and any components therein. It does not apply to the separate components, the sales packaging and the information sheets.

The dying colorants and inks used in the reusable menstrual cup shall not exceed 2% of total weight of the cup.

If dyed or printed on, the cup should comply with the following requirements:

- the content of antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, primary aromatic amines and polychlorinated biphenyl occurring as impurity in the dying colorants and inks shall be below the limits given in the Council of Europe's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food
  - The Council of Europe Resolution AP(89)1 on the use of colorants in plastic materials coming into contact with food is available at: https://rm.coe.int/16804f8648
- the dying colorants shall comply with BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities, or with the Swiss Ordinance 817.023.21 Annex 2 and Annex 10
  - The BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities is available at: https://www.bfr.bund.de/cm/349/IX-Colorants-for-Plastics-and-other-Polymers-Used-in-Commodities.pdf
  - The Swiss Ordinance 817.023.21 Annex 2 is available at: https://www.blv.admin.ch/dam/blv/fr/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmittelrecht2017/anhang2-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annexe_2.pdf
  - The Swiss Ordinance 817.023.21 Annex 10 is available at: https://www.blv.admin.ch/dam/blv/en/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/lebensmittelrecht2017/anhang10-verordnung-materialien-kontakt-lm-gg.pdf.download.pdf/Annex-10-ordinance-fdha-materials-and-articles-intended-to-come-into-contact-with-food-stuffs.pdf

⚠ *The dying colorants and inks used shall also comply with sub-criteria 4.1, 4.2 and 4.3*

Required documentation:

- Declaration of compliance with this sub-criterion (template available separately)
- Chemical supplier declarations, if relevant
- If dyes and/or inks are used, the following shall be provided:
  - documentation showing that impurities in the dying colorant or ink comply with the Council of Europe's Resolution AP (89) 1;
  - documentation showing that the used dyes are authorised according to BfR's recommendations IX. Colorants for Plastics and other Polymers Used in Commodities, Swiss Ordinance 817.023.21 Annex 2 and Annex 10 (if used in plastic materials).

4.3.4 Cyclosiloxanes

This sub-criterion applies to the final product and any components therein.

The maximum concentration of octamethyl cyclotetrasiloxane (D4 – CAS no.: 556-67-2), decamethyl cyclopentasiloxane (D5 – CAS no.: 541-02-6) and dodecamethylcyclohexasiloxane (D6 – CAS no.: 540-97-6) in the silicone raw materials is 100 ppm (0.01 % w/w).

⚠ *The 100 ppm limit is to be applied to each substance (D4, D5 and D6) separately*

Required documentation:

- Declaration of compliance with this sub-criterion (template available separately)
- Declaration from the suppliers, if relevant

Criterion 5: Packaging

This criterion aims at introducing certain percentages of recycled content and recyclability in the packaging of reusable menstrual cups.

⚠ *This criterion sets requirements for sales and grouped packaging.*

⚠ *Grouped packaging shall be avoided or made of only cardboard and/or paper.*

(a) Cardboard and/or paper used for packaging

⚠ *Sales packaging made of cardboard and/or paper shall contain a minimum 40% of recycled material.*

⚠ *Grouped packaging made of cardboard and/or paper shall contain a minimum 80% of recycled material.*

⚠ *The remaining share (100% minus recycled content percentage) of cardboard and/or paper used for the sales and grouped packaging shall be covered by valid Sustainable Forestry Management certificates issued by an independent third-party certification scheme such as FSC, PEFC or equivalent. The certification bodies issuing Sustainable Forestry Management certificates shall be accredited/recognised by that certification scheme.*

(b) Plastic used for packaging

⚠ *Until 31 December 2026, sales packaging made of plastic shall contain a minimum 20% recycled material.*

⚠ *From 1 January 2027, sales packaging made of plastic shall contain a minimum 35% recycled material.*

- Recycled content shall be verified by complying with the EN 45557 or ISO 14021.
- Plastic recycled content in the packaging shall comply with chain of custody standards such as ISO 22095 or EN 15343.
- Equivalent methods may be accepted if considered equivalent by a third-party, and shall be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material shall be provided.

(c) Recyclability

⚠ *The content of the sales packaging (either cardboard and/or paper or plastic) and grouped packaging (cardboard and/or paper) that is available for recycling shall be a minimum of 95% by weight, while 5% residuals shall be compatible with recycling.*

- Recyclability shall be verified by complying with the EN 13430 or ISO 18604.
- In addition, recyclability (availability and compatibility for recycling) of the packaging shall be tested by means of standard testing protocols. Cardboard and/or paper packaging recyclability shall be assessed through repulpability testing and in this case, the applicant shall demonstrate cardboard and/or paper packaging repulpability supported by the result(s) of test report(s) according to the PTS method PTS-RH 021, the ATICELCA 501 evaluation system or equivalent standard methods that are accepted by the competent body as providing data of equivalent scientific quality. Segregation schemes or controlled blending schemes like RecyClass shall be accepted as independent third-party certification for plastic packaging. Equivalent testing methods may be accepted if considered equivalent by a third-party.

(d) Additional requirements

- ⚠ *Utilisation of composite packaging (sales and grouped), mixed plastics or the coating of the cardboard and/or paper with plastics or metals are not allowed.*
- ⚠ *Recycled content and recyclability of sales and grouped packaging shall be indicated on the sales packaging.*

- Cardboard and/or paper used for the sales and grouped packaging:
  - ⚠ *The audited accounting documents shall be valid for the whole duration of the EU Ecolabel license.*
  - ⚠ *Competent bodies will check the accounting documents again twelve months after the awarding of the EU Ecolabel license.*
- Sales packaging made of plastic:
  - ⚠ *Competent bodies shall check the declaration of compliance specifying the percentages of plastic recycled content for sales packaging again after 1 January 2027.*

(e) Separate component: bag or pouch

Reusable menstrual cups shall be sold with a reusable bag or pouch made of 100% certified sustainable fibres.

- Independent third-party certification permitted for the reusable bag or pouch are FSC, PEFC, OEKO-TEX, GOTS, or equivalent schemes.

Required documentation:

- Declaration of compliance for recycled content and recyclability (template available).
- Audited accounting documents demonstrating the percentage (100% minus recycled content percentage) of the cardboard and/or paper used for the sales and grouped packaging is defined as certified material according to valid FSC, PEFC or equivalent schemes.
- Related supporting documentation regarding standard methods used for recycled content and recyclability compliance.
- Invoices demonstrating the purchase of the recycled material.
- High resolution photograph of the sales packaging (clearly visible information regarding recycled content and recyclability of the sales and grouped packaging).
- Declaration of compliance for the reusable bag or pouch (template available).

Criterion 6: Guidance on the disposal of the product and of the packaging

This criterion aims at providing the consumer with the correct information in order to dispose of the waste product and packaging.

The sales packaging shall contain guidance regarding disposal of the sales packaging, the grouped packaging (if any), the separate components and for the disposal of the used product. The following information shall be written or indicated through visual symbols on the sales packaging:

- ⚠ *that the sales packaging, the grouped packaging (if any), the separate components and the cup shall not be flushed into toilets, and*
- ⚠ *how to dispose correctly the sales packaging, the grouped packaging (if any), the separate components and the cup at the end of its life.*

Correct disposal is determined also by other factors than those purely related to the product itself (i.e. nature of the material to be disposed [plastic, cardboard/or paper]). For example, waste collection and management systems might differ within each Member State of the EU. Consequently, competent bodies should account for this potential heterogeneity at the time of interpreting what 'dispose correctly' means.

Required documentation:

- Declaration of compliance with the criterion (template available).
- High resolution photograph of the sales packaging (clearly visible information regarding disposal).

Criterion 7: Information on the use of the product

The user shall have access to instructions for the use of the RMC (e.g. information sheet, leaflet, packaging, QR code).

The user shall receive at least the following information:

(a) How to choose the right size of cup.

⚠ *Such information shall be placed where it can be accessed by the user before purchase (e.g. on the primary packaging).*

Cup sizes

Most reusable cups available on the market can be purchased in three sizes: S, M, and L.

Users may think that cup sizes refer to different sizes of the body, while they refer to whether the user has given birth or not, and how many times she has given birth. This should be explained to the user before she purchases the cup, to avoid the risk that the user discards a recently bought cup because of the wrong size.

(b) How to correctly wear the cup to avoid leakage and/or discomfort.

(c) How long to wear the cup before emptying it.

⚠ *Information on the longest wearing time shall be backed up by test studies.*

⚠ *This information shall be given in a visible way, e.g. via a logo or in bold characters, and shall be placed both on the packaging and on the instructions for use.*

(d) How to clean the cup before and after use during the same menstrual period, including, as a minimum, information about:

- the importance of washing the hands
- the need for boiling the cup (yes/no, and if yes for how long)
- the temperature of the water (hot/cold)
- the need for using soap (yes/no, and if yes how much)
- the duration of the cleaning

⚠ *This information should be backed up by test studies.*

(e) How to clean and store the cup between menstrual periods, including, as a minimum, information about:

- the importance of washing the hands
- the importance of boiling (and information on how long to boil the cup)
- the temperature of the water (hot/cold)
- the need for using soap (yes/no, and if yes how much)
- the duration of the cleaning

⚠ *This information should be backed up by test studies.*

(f) The lifetime of the cup.

⚠ *It should also be stated that eventual discolouring of the cup has no influence on its lifetime and function.*

(g) Information about the risk of developing toxic shock syndrome

⚠ *For the toxic shock syndrome, the importance of washing the hands and the longest wearing time of the cup shall be stated. Information shall also be given on how to recognise it what are the related symptoms, and how to react in case of developing the symptoms*

Required documentation:

- A sample of the information sheet/leaflet and, if relevant, the packaging sold with the cup displaying the information for the user
- Test/studies results justifying the longest wearing time of the cup and how to clean the cup during the same cycle and between cycles

⚠ *Examples of accepted studies are biological risk assessments and toxicology studies*

Criterion 8: Fitness for use and quality of the product

The aim of this criterion is to address the performance tests that RMC must undergo to fulfil all important characteristics and functions of the product.

The quality of products awarded with the EU Ecolabel is one of the most important aspects of the scheme, which must be considered in order to prevent creating the image that EU Ecolabel products are environmentally friendly but poor in performance/inefficient.

The effectiveness /quality of the final product shall be satisfactory and at least equivalent to that of products already on the market.

Fitness for use shall be tested with respect to the characteristics and the parameters reported in Table 5. Performance thresholds shall be matched, where these have been identified.

Fitness for use shall be tested with respect to the technical tests referred to as for biocompatibility of the materials used for the manufacturing of reusable menstrual cups. Biocompatibility test shall provide the biological evaluation of cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days).

Table 5 : Characteristics and parameters describing the fitness for use of the product to be tested

Characteristic		Testing practice required (performance threshold)
In-use tests	U1. Leakage protection	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)
	U2. Fit and comfort	
	U3. Overall performance	
Technical tests	T1. Biocompatibility	No relevant biological effects in the studies performed for cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days) as indicated by ISO 10993. Alternatively compliance with USP Class VI standard (acute systemic toxicity, intracutaneous toxicity and implantation test) could be reported.

- In-use and technical tests guidelines:

In-use tests shall be conducted for the specific products for which the EU Ecolabel application is made. Nevertheless, if it can be demonstrated that products have the same performance, it can be enough to test only one size or a representative mix of sizes per each product design.

Technical tests shall be conducted for the material(s) used for the manufacturing of reusable menstrual cups for which the EU Ecolabel application is made. If it can be demonstrated that several reusable menstrual

cups models are manufactured with the same material, it can be enough to test that material only once. Reusable menstrual cups are not requested to undergo technical tests, only the materials used in the production of cups (this includes silicones, cross-linked silicone elastomers, other elastomers, colorants used and any other materials).

Special care shall be taken regarding sampling, transport and storage of the materials and products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or packaging, unless alteration can be excluded.

Information on testing shall be made available to the competent bodies under the respect of confidentiality issues. Test results shall be clearly explained and presented in language, units and symbols that are understandable to the data user. The following elements shall be specified: place and date of the tests; criteria used to select the materials tested and their representativeness; selected testing characteristics and, if applicable, the reasons why some were not included; test methods used and their limitations if any. Clear guidelines on the use of test results shall be provided.

- Additional guidelines for in-use tests:

— Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019[5], ASTM E1958-07e1[6] or equivalent).

— Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible, and shall be realised in normal conditions of use of the product.

— The recommended number of testers shall be at least 30. All the individuals participating to the survey shall be current users of the specific type/size of product tested.

— A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age and countries shall be clearly stated.

— Sick individuals and those with a chronic condition shall not participate in the test. In cases where individuals become ill during the course of the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.

— For all in-use tests (leakage protection, fit and comfort and overall performance), 80 % of the consumers testing the product shall rate the performance as satisfactory, with a rate above 60 assigned by the consumer (on a quantitative scale from 1 to 100). Alternatively 80% of the consumers testing the product shall rate it as good or very good (among five qualitative options: very poor, poor, average, good, very good).

— The results shall be statistically evaluated after the user trial has been completed.

— External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated.

[5] https://www.boutique.afnor.org/en-gb/standard/q34019/sanitary-and-domestic-articles-test-method-under-conditions-of-use-for-chil/fa039217/11448

[6] https://www.astm.org/e1958-07e01.html

❖ Additional requirements for technical tests:

— Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.

— Technical tests shall be performed in accordance to ISO 10993 series or the USP Class VI standard.

— Test methods whose scope and requirement standards is considered equivalent to the one of the named national and international standards and whose equivalency have been confirmed by an independent third party shall be accepted.

⚠ *Weight, dimensions and design features of the product shall be described and provided in accordance with information provided in the application general assessment and verification text.*

Required documentation:

- Declaration of compliance with in-use tests (template available).
- Declaration of compliance with technical tests (template available).
- Test report for in-use tests.
- Test report for technical tests.

⚠ *A test report shall be provided describing test methods, test results and data used.*

⚠ *Tests shall be carried out by laboratories certified to implement quality management systems.*

Criterion 9: Corporate Social Responsibility with regard to labour aspects

The aim of this criterion is to set guidelines to ensure that the minimum labour standard requirements have been fulfilled by companies applying for the EU Ecolabel, independently from national laws.

⚠ *This criterion sets requirements applying to the final reusable menstrual cup manufacturing site.*

Applicants shall obtain third-party verification supported by site audit(s) that the following principles included in the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy[7]; the UN Global Compact (Pillar 2)[8]; the UN Guiding Principles on Business and Human Rights[9]; and; the OECD Guidelines for Multinational Enterprises[10], have been respected:

(i) Child Labour:

— Minimum Age Convention, 1973 (No 138)

— Worst Forms of Child Labour Convention, 1999 (No 182)

(ii) Forced and Compulsory Labour:

— Forced Labour Convention, 1930 (No 29) and 2014 Protocol to the Forced Labour Convention

— Abolition of Forced Labour Convention, 1957 (No 105)

(iii) Freedom of Association and Right to Collective Bargaining:

— Freedom of Association and Protection of the Right to Organise Convention, 1948 (No 87)

— Right to Organise and Collective Bargaining Convention, 1949 (No 98)

(iv) Discrimination:

— Equal Remuneration Convention, 1951 (No 100)

— Discrimination (Employment and Occupation) Convention, 1958 (No 111)

Supplementary provisions:

(v) Working Hours:

— ILO Hours of Work (Industry) Convention, 1919 (No 1)

— ILO Weekly Rest (Industry) Convention, 1921 (No 14)

7 ILO NORMLEX (http://www.ilo.org/dyn/normlex/en) and supporting guidance.

8 United Nations Global Compact (Pillar 2), https://www.unglobalcompact.org/what-is-gc/participants/141550.

9 Guiding Principles for Business and Human Rights, https://www.unglobalcompact.org/library/2.

10 OECD Guidelines for Multinational Enterprises, https://www.oecd.org/daf/inv/mne/48004323.pdf.

(vi) Remuneration:

— ILO Minimum Wage Fixing Convention, 1970 (No 131)

— ILO Holidays with Pay Convention (Revised), 1970 (No 132)

— Living wage: The applicant shall ensure that wages (excluding any taxes, bonuses, allowances, or overtime wages) paid for a normal work week (not exceeding 48 hours) shall be sufficient to afford basic needs (housing, energy, nutrition, clothing, health care, education, potable water, childcare, and transportation) of worker and of a family of four people, and to provide some discretionary income. Implementation shall be audited with reference to the SA8000 guidance on 'Remuneration'.

(vii) Health & Safety:

— ILO Safety in the use of chemicals at work Convention, 1981 (No 170)

— ILO Occupational Safety and Health Convention, 1990 (No 155)

— ILO Working Environment (Air Pollution, Noise and Vibration) Convention, 1977 (No 148)

(viii) Social protection and inclusion:

— ILO Medical Care and Sickness Benefits Convention, 1969 (No 130)

— ILO Social Security (Minimum Standards) Convention, 1952 (No 102)

— ILO Employment Injury Benefits Convention, 1964 (No 121)

— ILO Equality of Treatment (Accident Compensation) Convention, 1925 (No 19)

— ILO Maternity Protection Convention, 2000 (No 183)

(ix) Fair dismissal:

— ILO Termination of Employment Convention, 1982 (No 158).

⚠ *In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall not restrict workers from developing alternative mechanisms to express their grievances and protect their rights regarding working conditions and terms of employment, and shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.*

⚠ *The audit process shall include consultation with external industry-independent organisation stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. Meaningful consultations shall take place with at least two stakeholders from two different subgroups. In locations where national law cannot ensure adequacy of corporate social responsibility with the aforementioned international conventions, the audit process shall include third-party site audits composed of unannounced spot inspections by industry-independent evaluators.*

⚠ *During the validity period of the EU Ecolabel license, the applicant shall publish the aggregated results and key findings from the audits (including details on (a) how many and*

how serious violations of each labour rights and OHS standard; (b) strategy for remediation – where remediation includes prevention per UNGP concept; (c) assessment of root causes of persistent violations resulting from stakeholder consultation – who was consulted, what issues were raised, how did this influence the corrective action plan), online in order to provide evidence of their performance to interested consumers.

Third party verification of factory sites to the following standards and codes of conduct shall be recognised as their core criteria reflect the ILO standards:

Equivalent codes of conduct:

- OECD Guidelines for Multi-National Enterprises: Recommendations on human rights and on employment and industrial relations https://www.oecd.org/corporate/mne/
- The United Nations Global Compact: Principles on Human rights and Labour https://unglobalcompact.org/what-is-gc/mission/principles
- The Joint Initiative on Corporate Accountability and Workers Rights (JO-IN): the Draft Code of Labour Practice https://jo-in.org/pub/about.shtml

Equivalent standards:

- ISO 26000: Human rights and Labour practice components https://www.iso.org/iso-26000-social-responsibility.html
- Social Accountability 8000 (SA8000) https://sa-intl.org/
- Ethical Trading Initiative (ETI) https://www.ethicaltrade.org/
- Fair Wear Foundation (FWF) https://www.fairwear.org/
- Business Social Compliance Initiative (BSCI) https://www.amfori.org/content/amfori-bsci
- Fair Labor Association (FLA) https://www.fairlabor.org/

⚠ *Third-party site audits shall be carried out by auditors qualified to assess the compliance of the industry manufacturing sites with social standards or codes of conduct or, in countries where the ILO Labour Inspection Convention, 1947 (No 81) has been ratified and ILO supervision indicates that the national labour inspection system is effective and where the scope of the inspection systems covers the areas listed above, by labour inspector(s) appointed by a public authority.*

⚠ *The third-party certifications shall be not more than 12 months old, on the date of application. The applicant shall demonstrate third party verification of compliance, using independent verification or documentary evidence, including site visits by auditors during the Ecolabel verification process for production sites in the supply chain for the licensed products. These shall take place upon application and subsequently during the license period if new production sites are introduced.*

Required documentation:

- Declaration of compliance with the criterion (template available).
- Copies of the most recent version of the code of conduct for each final product assembly plant for the model(s) to be ecolabelled (consistent with the provisions specified above)
- Copies of the supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled (adding a web link to where online publication of the results and findings can be found)
- Valid certifications from third-party schemes or inspection processes of audit compliance for each final product assembly plant for the model(s) to be ecolabelled (consistent with the provisions specified above)

Criterion 10: Information appearing on the EU Ecolabel

This criterion aims to inform consumers about the award of the EU Ecolabel to the product, about some environmental requirements the product is complying with, to make easier the environmentally friendly choice.

In this line, the EU Ecolabel logo may be displayed on the sales packaging of the product.

If the optional label with text box is used, it shall contain the following three statements:

- 'Designed to reduce impact on the environment',
- 'Fulfils strict requirements on harmful substances',
- 'Verified performance',

> ⚠ *The applicant shall follow the instructions on how to use the EU Ecolabel logo as provided in the EU Ecolabel Logo Guidelines:*
> *http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf*

Required documentation:

- Declaration of compliance with the criterion (template available).
- High resolution photograph of the product sales packaging that clearly shows the EU Ecolabel logo, the registration/license number and, where relevant, the statements that can be displayed together with the logo.