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ANNEX II

EU Ecolabel criteria for awarding the EU Ecolabel to reusable menstrual cups

Assessment and verification requirements

For the EU Ecolabel to be awarded to a specific product, applicants must comply with each requirement.

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 granted shall be notified to Competent Bodies, together with supporting information to enable verification of continued compliance with the criteria.

As pre-requisite, the product must meet all respective legal requirements of the Member State 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 to the competent body:

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

- a description of the primary packaging, together with its total weight, if applicable;

- a description of the secondary packaging, together with its total weight;

- a description of the additional components, together with its total weight;

- the components, materials and additives used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

A written confirmation from the applicant that all the criteria are fulfilled shall also be required for the assessment.

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For the purposes of this Annex, the following definitions shall apply:

(1) ‘Additional component’ means any component (with protective or hygienic function) that is removed before the use of the product, e.g. the individual wrap or film where some absorbent hygiene products are contained within the primary packaging (mainly for tampons and sanitary pads), the release liner or paper in baby diapers and sanitary pads, or the applicator for tampons. The additional component can also be the cloth bag were menstrual cups are usually sold with.

(2) ‘Impurities’ means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg). *[to be added to the User Manual: 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.]*

(4) ‘Ingoing substance’ means all substances included in the final product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.

(5) 'Plastic materials', also referred to as 'Plastics', means polymeric materials to which additives may have been added. The definition includes polymer-based rubber items and bio-based and biodegradable plastics regardless of whether they are derived from biomass or are intended to biodegrade over time.

(6) ‘Primary packaging’, also known as sales packaging, means packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase;

(8) ‘Product unit’ means the smallest item that can be used by the consumer and that fulfils the product’s function.

(9) ‘Recyclability capacity’ 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) sourced from post-consumer and/or post-industrial recycled material.

(11) ‘Recycling’ means, in accordance with Article 3 of Directive 2008/98/EC of the European Parliament and of the Council[1], 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) ‘Secondary packaging’ means grouped packaging, i.e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics.

(13) ‘Substances identified to have endocrine disrupting properties’ means substances which have been identified to have endocrine disrupting properties (human health and/or

[1] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008L0098-20180705&from=EN

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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([2]) or (EC) No 1107/2009([3]) of the European Parliament and of the Council;

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

- A polymerisation process such as poly-addition or poly-condensation or by any other similar process of monomers and other starting substances;
- Chemical modification of natural or synthetic macromolecules;
- Microbial fermentation.

(15) 'Transport packaging', also known as tertiary packaging, means packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packagings in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers.

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2 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20210610

3 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

Criterion 1: Emissions during production of the raw material

Criterion 1.1: Emissions of dust and of chlorides to air

Criterion 1.1(a) Dust

(i) This requirement applies to silicon only. The storage and handling of the elemental silicon raw material shall apply at least one of the following techniques:

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

(ii) This requirement applies to both silicon and other elastomers. The yearly average from channelled emissions of dust shall be below 5 mg/Nm^3. The dust emissions should be continuously monitored.

Criterion 1.1(b) Chlorides

(i) This requirement applies to silicon only. The off-gases from the methyl chloride, direct synthesis and distillation process steps shall undergo thermal oxidation followed by scrubbing. The thermal oxidation shall be authorised to burn chlorinated compounds.

(ii) This requirement applies to both silicon and other elastomers. PCDD/F emissions shall be below 0.01 ng TEQ/Nm^3. Monitoring of the PCDD/F emissions should take place every six months.

***Assessment and verification**:*

The applicant shall provide a declaration of compliance from the raw material supplier with criterion 1.1. In addition:

- *To show compliance with criterion 1.1(a).i, the silicon supplier shall indicate which measure is used on site, providing pictures or projects of the measure installed as supplementary data;*
- *To show compliance with criterion 1.1(a).ii, the raw material supplier shall provide the results of the dust measurements taken on site, together with the yearly average of the dust emission. For the production of silicon, the measurement shall cover grinding, storage and handling of elemental silicon as a minimum;*
- *To show compliance with criterion 1.1(b).i, the silicon supplier shall provide details on the processing of the off-gases from the methyl chloride, direct synthesis and distillation steps,;*

To show compliance with criterion 1.1(b).ii, the raw material supplier shall provide the results of the PCDD/F emissions measurements of the treated gases.

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Criterion 1.2: Emissions of copper and zinc to water

This criterion applies to silicon only.

The water effluents from the PDMS production step shall be pre-treated by precipitation/flocculation under alkaline conditions followed by sedimentation and filtration. This shall include:

- dewatering the sludge before disposal; and
- recovering the solid metal residues in metal recovery plants; or
- disposing of the sludge via incineration or landfill.

The concentration of copper in the treated effluent shall be below 0.5 mg/l, while the concentration of zinc shall be below 2 mg/l.

***Assessment and verification**:*

The applicant shall provide a declaration of compliance from the silicon supplier with criterion 1.2, together with a proof that the plant has in place a waste water system consisting of a precipitation/flocculation step followed by a sedimentation step. Moreover, the silicon supplier shall provide the measurement results for copper and zinc in the treated effluent.

Criterion 1.3: Emissions of CO_2

This criterion applies to silicon only.

CO_2 emissions from the production of the silicon shall not exceed 1.3 kg per kg silicon, including emissions from the production of electricity (whether on-site or off-site). Reference emission values according to Table 1 shall be used in the calculation of CO_2 emission from fuels. If needed, CO_2 emission factors for other fuels can be found in Annex VI to Regulation (EU) 2018/2066.

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

Fuel	**CO_2 fossil emissions**	**Unit**	**Reference**
Coal	94.6	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Crude oil	73.3	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 1	74.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Fuel oil 2-5	77.4	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
LPG	63.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066
Natural Gas	56.1	g CO_2 fossil/MJ	Regulation (EU) 2018/2066

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Grid Electricity	376	g CO_2 fossil/kWh	Regulation (EU) 2019/331

***Assessment and verification**:*

The applicant shall provide data and detailed calculations showing compliance with this criterion, together with related supporting documentation.

The CO_2 emission data shall include all sources of non-renewable fuels used during the production of the raw material, including the emissions from the production of electricity (whether on-site or off-site).

Factors accepted by the authorities in European Union Emissions Trading System (EU ETS) shall also be accepted. The period for the calculations or mass balances shall be based on the production over 12 months. In case of a new or a rebuilt production plant, the calculations shall be based on at least 45 subsequent days of stable running of the plant. The calculations shall be representative of the respective campaign.

For grid electricity, the value provided above (the European average) shall be used unless the applicant presents documentation establishing that energy from renewable sources is purchased, in which case the applicant may use the factor for the purchased electricity (contract for specified electricity or National Inventories), instead of the value quoted in Table 1. The documentation used as proof of compliance shall include technical specifications that indicate the average value (i.e. copy of a contract).

The amount of energy from renewable sources purchased and used for the production processes counts as zero CO_2 emission when calculating CO_2 emissions. Similarly, energy from nuclear plants counts as zero CO_2 emission. The applicant shall provide appropriate documentation that this kind of energy is actually used at the plant or has been externally purchased.

Criterion 2: Environmental management of production

All plants producing either raw materials (silicone or other elastomers) or the reusable menstrual cups shall have systems for the implementation of:

— water-saving (e.g. monitoring of water flow in a facility and circulating the water in closed systems),

— integrated waste management plan to optimise prevention, reuse, recycling, recovery and final disposal of waste (e.g. separation of different waste fractions),

— optimisation of energy efficiency and energy management (e.g. reuse /recovery of surplus energy generated during the manufacture of the cups).

Assessment and verification:

The applicant shall provide a declaration of compliance with the cited requirement from (1) the producer of raw materials (silicone or other elastomers) and (2) from manufacturer of reusable menstrual cups. The declaration shall be supported by a report describing in detail the procedures adopted by the suppliers in order to fulfil the requirement for each of the sites concerned in accordance with standards, such as ISO 14001 and/or ISO 50001.

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Criterion 3: Material efficiency in the manufacturing

The quantity of waste generated during the manufacture and packaging of reusable menstrual cups, at the net of the fraction that is reused or converted into useful materials and/or energy, shall not exceed:

— 8 % by weight of the end products

Assessment and verification:

The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy.

Calculations shall be shown in accordance with ISO 14025 and the applicant shall present all of the following parameters concerning:

— *the weight of product and packaging,*

— *all the waste streams generated during the manufacture, and*

— *the respective treatment processing (e.g. recycling, incineration), including the fraction of recovered waste and that disposed of.*

The net waste shall be calculated as the difference between the amount of waste produced and the amount of waste recovered.

Criterion 4: Excluded and restricted substances

Criterion 4.1: Restrictions on substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4]

Unless derogated in Table 3, the final product, and any component articles therein, shall not contain ingoing substances (alone or in mixtures) that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 2, in accordance with Regulation (EC) No 1272/2008.

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

[4] *Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)*

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	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 on 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

Table 3. Derogations to restrictions on substances with a harmonised classification under Regulation (EC) No 1272/2008 and applicable conditions

Substance type	**Applicability**	**Derogated hazard class, category and hazard statement code**	**Derogation conditions**
Titanium dioxide (nano-form)	Pigment	H351: Suspected of causing cancer	It cannot be used in powder or spray form

Moreover the final product, and any component articles therein, shall not contain ingoing substances (alone or in mixtures) in concentrations greater than 0,010% (weight by weight)

that are assigned any of the hazard classes, categories and associated hazard statement codes stated in Table 4, in accordance with Regulation (EC) No 1272/2008.

Table 4. 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 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 criterion does not apply to:

— substances not included in the scope of Regulation (EC) No 1907/200618 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.

In order to determine if this exclusion applies, the applicant shall screen any ingoing substances or mixtures present in the product.

***Assessment and verification**:*

The applicant shall provide a signed declaration of compliance with sub-criterion 4.1, together with a list of all chemicals used in their production process, their safety data sheet or chemical supplier declaration and any relevant declarations that demonstrate the compliance with the requirement.

For restricted substances and unavoidable impurities with a restricted classification, the concentration of the restricted substance or impurity and an assumed retention factor of 100%, shall be used to estimate the quantity of the restricted substance or impurity remaining in the final product. [to be added in the User Manual: impurities can be present in the final

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product up to 0.0100% w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities]

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

Since multiple products or potential products using the same process chemicals may be covered by one license, the calculation only needs to be presented for each impurity for the worst-case product or component article covered by the EU Ecolabel license (e.g. the most heavily printed component article when screening for inks with restricted classifications).

The above evidence can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

Criterion 4.2: Substances of Very High Concern (SVHCs)

The final product, and any component articles therein, shall not contain ingoing substances (alone 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[5] 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.

Assessment and verification:

The applicant shall provide a signed declaration that the final product does not contain any SVHCs. The declaration shall be supported by safety data sheets of all supplied chemicals and materials used to produce the final product.

The list of substances identified as SVHCs and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

Reference to the list shall be made on the submission date of the EU Ecolabel application.

For unavoidable impurities identified as SVHCs, the concentration of the impurity and an assumed retention factor of 100%, shall be used to estimate the quantity of the SVHC impurity remaining in the final product. [to be added in the User Manual: impurities can be present in the final product up to 0.0100% w/w. Substances known to be released or to degrade from ingoing substances are considered ingoing substances and not impurities]

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

Criterion 4.3: Other specific restrictions

Criterion 4.3(a): Specified excluded substances

The following substances shall not be included (alone or in mixtures) in the final product, nor in any component articles therein:

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[5] *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)*

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i. 5-chloro-2-methyl-4-isothiazoline-3-one (CMIT);

ii. Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];

iii. Formaldehyde and formaldehyde releasers;

iv. Methylisothiazolinone (MIT)

v. Nanosilver

vi. Nitromusks and Polycyclic musks;

vii. Organotin compounds;

viii. Parabens;

ix. Phthalates;

x. Substances identified to have endocrine disrupting properties;

xi. 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;

xii. Triclosan.

Criterion 4.3(b): Fragrances

Fragrances shall not be added to the final product, nor to any component thereof, nor to the packaging.

Criterion 4.3(c): Inks and dyes

The dying colorants and inks used in the reusable menstrual cup shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008.

In addition, 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 European Council's Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food(*).

The dying colorants and inks used shall also comply with sub-criteria 4.1 and 4.2.

Criterion 4.3(d): Further restrictions applying to synthetic polymers and plastic materials

(i) Contents of lead, cadmium, hexavalent chromium and related compounds shall be lower than 0.01 % weight by weight (100 ppm) of the mass of each plastic material and synthetic polymer used in the product.

(ii) Additives used in plastics in concentration above 0,10 % weight by weight shall not be classified with any of the below listed hazard statements, in accordance with the classification rules in Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1):

- carcinogenic, mutagenic or toxic for reproduction, categories 1a, 1b and 2 (H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df),
- acutely toxic, categories 1 and 2 (H300, H310, H330, H304),

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- toxic to specific target organs (STOT), category 1: (H370, H372),
- hazardous to the aquatic environment, categories 1 and 2 (H400, H410, H411).

Criterion 4.3(e): Cyclosiloxanes

Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and Dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the final product in concentrations above 10 ppm (0,001 % w/w). The 10 ppm limit is to be applied to each substance separately.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with all above sub-criteria, supported by declarations from suppliers whenever relevant, and the following supporting evidence:

To demonstrate compliance with sub-criteria 4.3(a) and 4.3(d), the applicant shall provide:

(i) safety data sheets (SDS) of any substance/mixture and their concentration in the final product;

(ii) a written confirmation that sub-criteria 4.3(a), and 4.3(d) are fulfilled.

To demonstrate compliance with criterion 4.3(c), documentation shall be provided to ensure that the colouring agent is approved for use in food.

To demonstrate compliance with sub-criterion 4.3(e), the applicant shall provide a declaration from the supplier that the requirement has been fulfilled.

The above evidence may also be provided directly to competent bodies by any supplier in the applicant's product supply chain.

Notes:

[1] Substance name = “Alkyl phenol”, under: https://echa.europa.eu/es/advanced-search-for-chemicals

Criterion 5: Packaging

This criterion applies to primary and secondary packaging, as defined in European Parliament and Council Directive 94/62/EC ([1]). It also applies to the additional component, i.e. the bag where reusable menstrual cups are sold with.

Criterion 5.1. Primary and secondary packaging

— Cardboard and paper used for the primary and secondary packaging of reusable menstrual cups shall be made of 100 % recycled material.

— Plastic used for the primary and secondary packaging of reusable menstrual cups shall be made of at least 80 % recycled material.

— Only unmixed plastic without any coating is permitted when using plastic packaging.

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— Utilisation of composite packaging (primary or secondary) or the coating of the cardboard/paper with plastics or metals are not allowed.

— If primary or secondary packaging is sourced from bio-based plastic, sub-criterion 4.2 of absorbent hygiene products (annex I) shall apply.

— Cardboard and paper or plastic used for the primary and secondary packaging shall be designed for recycling in at least 95%.

Criterion 5.2. Additional component: cotton bag or pouch

Reusable menstrual cups shall be sold with a reusable bag or pouch made of 100% organic cotton.

(a) Cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007 ([2]), the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the Union. The organic cotton content may include organically grown cotton and transitional organic cotton.

(b) Cotton shall not be bleached with the use of elemental chlorine gas (Cl_2).

Assessment and verification:

5.1. Primary and secondary packaging

The applicant shall submit (i) a signed declaration of compliance specifying the percentages of recycled content of the primary and secondary packaging; (ii) a declaration of compliance specifying the recyclability capacity of the primary and secondary packaging; and (iii) a high resolution image of the primary packaging (where information regarding recyclable content and recyclability appear clearly).

Recycled content must be verified by complying with the EN 45557 or ISO 14021 while recyclability must be verified by complying with the EN 13430 or ISO 18604.

Equivalent methods may be accepted as test methods if considered equivalent by a third-party, and must be accompanied by detailed explanations showing compliance with this requirement and related supporting documentation. Invoices demonstrating the purchase of the recycled material must be provided.

5.2. Additional component: cotton bag or pouch

(a) Organic cotton content shall be certified by an independent control Body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007, the US National Organic Programme (NOP) or those set by other trade partners. Verification shall be provided on an annual basis for each country of origin.

(b) The applicant shall provide a declaration from the supplier that elemental chlorine gas is not used.

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

The primary packaging must contain information on the guidance of the primary packaging, the secondary packaging (if any), the additional components and the product disposal. The

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following information shall be written or indicated through visual symbols on the primary packaging:

— that the primary packaging, the secondary packaging (if any), the additional components and the cup must not be flushed into toilets, and

— how to dispose the primary packaging, the secondary packaging (if any), the additional components and the cup (at the end of its life) correctly.

***Assessment and verification**:*

The applicant shall provide a high resolution image of the primary packaging (where information regarding disposal appear clearly).

Criterion 7: Fitness for use and quality of the product

The efficiency/quality of the product shall be at least as satisfactory as an equivalent product already on the market.

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

Reusable menstrual cups shall undergo the following in-use tests: leakage protection, fit and comfort and overall performance.

Moreover, 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 must provide the biological evaluation of cytotoxicity, hemolysis, 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, hemolysis, 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.

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***Assessment and verification**:*

A test report shall be provided describing test methods, test results and data used. Tests shall be carried out laboratories certified to implement quality management systems, no matter if internal or external.

In-use tests shall be conducted for the specific products applying for the EU Ecolabel. 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 applying for the EU Ecolabel. If it can be demonstrated that several reusable menstrual cups models are manufactured with the same material, it can be enough to test only one material.

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 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 products 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 user tests:

— *Sampling, test design, panel recruitment and the analysis of test results shall comply with standard statistical practices (AFNOR Q 34-019, ASTM E1958-07e1 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 should 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, which could for instance mean that a rate above 60 is assigned by the consumer (on a quantitative scale from 1 to 100) or that the product has been assessed 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.*

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

Additional requirements for technical tests.

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

— *A minimum of five samples shall be tested. Average results shall be reported together with indication of the standard deviation.*

— *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.

Criterion 8: Information for the user

The manufacturer shall make sure that the user receives at least the following information:

i. How to choose the right size of cup. Such information must be placed where it can be accessed by the user before purchase (e.g. on the packaging).

ii. How to correctly wear the cup to avoid leakage and/or discomfort.

iii. How long to wear the cup before emptying it.

iv. How to clean the cup before and after use during the same menstrual cycle, including, as a minimum, information about the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning. It should also be mentioned that boiling is not needed when cleaning the cup during the same menstrual cycle.

v. How to clean and store the cup between menstrual cycles, including, as a minimum, information about the need for boiling (yes/no, and if yes for how long), the water (hot/cold), the soap (yes/no, and if yes how much) and the duration of the cleaning.

vi. How long it is possible to use the cup (the lifetime of the cup). It should moreover be stated that eventual discolouring of the cup has no influence on its lifetime and function.

If the user is recommended to use soap, the following sentence should be included: "*use the soap sparingly in order to minimise the impact on the environment*".

Moreover, information about the risk of developing toxic shock syndrome must be provided, including how to recognise it (what are the symptoms) and how to react in case of developing it.

Assessment and verification*:*

The applicant shall provide the competent body with a sample of the information sheet and, if relevant, the packaging sold with the cup displaying the information for the user.

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Criterion 9: Corporate Social Responsibility with regard to Labour Aspects

Requirements in this criterion shall apply to the final product assembly site.

These standards shall be communicated to production sites along the supply chain used to manufacture the final product.

Having regard to the International Labour Organisation's (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy (*), the UN Global Compact (Pillar 2) (*), the UN Guiding Principles on Business and Human Rights (*) and the OECD Guidelines for Multinational Enterprises (*), the applicant shall obtain third-party verification supported by site audit(s) that the applicable principles included in the ILO's fundamental conventions and the supplementary provisions below have been respected at the final AHP assembly site for the product.

Fundamental conventions of the ILO:

(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).

(vi) Remuneration:

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

— Living wage: The applicant shall ensure that wages paid for a normal working week shall always meet at least legal or industry minimum standards, are sufficient to meet the basic needs of personnel and 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).

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In locations where the right to freedom of association and collective bargaining are restricted under law, the company shall recognise legitimate employee associations with whom it can enter into dialogue about workplace issues.

The audit process shall include consultation with external stakeholders in local areas around sites, including trade unions, community organisations, NGOs and labour experts. The applicant shall publish the aggregated results and key findings from the audit online in order to provide evidence of their supplier's performance to interested consumers.

Assessment and verification:

The applicant shall provide a declaration of compliance together with copies of certificates and a supporting audit reports for each final product assembly plant for the model(s) to be ecolabelled.

The third-party site audit shall be carried out by private auditors qualified to assess the compliance of the AHP industry supply chain 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 ([1]) and where the scope of the inspection systems covers the areas listed above, by labour inspector(s) appointed by a national authority.

Certificate(s), not dated more than 12 months prior to the application, from schemes or processes that audit compliance with the applicable principles of the listed fundamental ILO conventions, together with the supplementary provisions on working hours, remuneration and health and safety, shall be accepted.

(References*

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

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

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

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

Criterion 10: Information appearing on the EU Ecolabel

The EU Ecolabel logo may be applied on the primary packaging of the product. The optional label with box shall contain the following text:

— ‘Product designed to reduce environmental impact’,

— ‘Restricted use of hazardous substances’,

— ‘Verified performance’.

The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines:

http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

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Assessment and verification:

The applicant shall provide a declaration of compliance with the requirement and visual evidence (photograph of the product). The photograph provided must be a high resolution image of the product primary packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.

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