Commission Decision of 24 October 2014 establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products (notified under document C(2014) 7735) (Text with EEA relevance) (2014/763/EU)

COMMISSION DECISION

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establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products

(notified under document C(2014) 7735)

(Text with EEA relevance)

(2014/763/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel[(1)], and in particular Article 8(2) thereof,

After consulting the European Union Eco-labelling Board,

Whereas:

(1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to products which have a reduced environmental impact during their entire life cycle.

(2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.

(3) The criteria, as well as the related assessment and verification requirements should be valid for four years from the date of adoption of this Decision, taking into account the innovation cycle for this product group.

(4) Since consumption of materials can contribute significantly to the overall environmental impacts of absorbent hygiene products, it is appropriate to establish EU Ecolabel criteria for this product group. The criteria should, in particular, promote sustainable sourcing of materials, limited use of hazardous substances, high-quality and high-performance products which are fit-for-use and are designed to minimise waste production.

(5) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

Article 1

1 The product group ‘absorbent hygiene products’ shall comprise baby diapers, feminine care pads, tampons and nursing pads (also known as breast pads), which are disposable and composed of a mix of natural fibres and polymers, with the fibre content lower than 90 % by weight (except for tampons).

2 The product group shall not include incontinence products and any other type of products falling under the scope of Council Directive 93/42/EEC[(2)].

Article 2

For the purpose of this Decision, the following definitions shall apply:

(1) ‘cellulose pulp’ means a fibrous material mainly composed of cellulose and obtained from the treatment of lignocellulosic materials with one or more aqueous solutions of pulping and/or bleaching chemicals;

(2) ‘optical brightener’ and ‘fluorescent whitening agent’ mean any additives used with the only purpose of ‘whitening’ or ‘brightening’ the material;

(3) ‘plastic materials’, also referred to as ‘plastics’, means synthetic polymers to which additives or other substances may have been added which can be moulded and used as main structural component of final materials and articles;

(4) ‘synthetic polymers’ means macromolecular substances, other than cellulose pulp, intentionally obtained either by a polymerisation process or chemical modification of natural or synthetic macromolecules or microbial fermentation;

(5) ‘super absorbent polymers’ means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass.

Article 3

In order to be awarded the EU Ecolabel under Regulation (EC) No 66/2010, a product shall fall within the product group ‘absorbent hygiene products’ as defined in Article 1 of this Decision and shall comply with the criteria as well as the related assessment and verification requirements set out in the Annex.

Article 4

The criteria for the product group ‘absorbent hygiene products’, as well as the related assessment and verification requirements, shall be valid for four years from the date of adoption of this Decision.

Article 5

For administrative purposes, the code number assigned to the product group ‘absorbent hygiene products’ shall be ‘047’.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 24 October 2014.

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

ASSESSMENT AND VERIFICATION REQUIREMENTS

The 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 or his supplier or both.

Competent bodies shall preferentially recognise tests which are accredited according to ISO 17025 and verifications performed by bodies which are accredited under the EN 45011 standard or an equivalent international standard.

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.

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

Criteria for awarding the EU Ecolabel to absorbent hygiene products:

1. Product description
2. Fluff pulp
3. Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)
4. Cotton and other natural cellulosic seed fibres
5. Plastic materials and superabsorbent polymers
6. Other materials and components
7. Excluded or limited substances or mixtures
8. Material efficiency in the manufacturing
9. Guidance on the product disposal
10. Fitness for use and quality of the product
11. Social aspects
12. Information appearing on the EU Ecolabel

The EU Ecolabel criteria shall reflect the best environmental performing products on the market of absorbent hygiene products.

Criterion 1. Product description

A description of the product and packaging shall be provided (product name, classification, functionalities) together with information on all of the following characteristics:

— the total weight of the product and packaging,

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

Information on the weight of the product shall be also displayed in the packaging.
Assessment and verification:

The applicant shall provide a sample of the product and a report including the technical description and the weight of the product and of each component, material and additive used.

Criterion 2. Fluff pulp

2.1. *Sourcing*

All pulp fibres shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

A minimum of 25 % pulp fibres shall be covered by valid Sustainable Forestry Management certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

The remaining proportion of pulp fibres shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification bodies issuing forest and/or chain of custody certificates shall be accredited/ recognised by that certification scheme.
Assessment and verification:

The applicant shall obtain from the pulp manufacturer(s) valid, independently certified chain of custody certificates demonstrating that wood fibres have been grown according to Sustainable Forestry Management principles and/or are from legal and controlled sources. FSC, PEFC or equivalent schemes shall be accepted as independent third party certification.

2.2. *Bleaching*

The pulp used in the product shall not be bleached with the use of chlorine gas. The total amount of AOX emissions from pulp manufacturing shall not exceed 0,170 kg/ADT.
Assessment and verification:

The applicant shall provide a declaration from the pulp manufacturer that chlorine gas was not used and a test report showing compliance with the AOX limit value. ISO 9562 or the equivalent EPA 1650C shall be accepted as test methods, accompanied by detailed calculations showing compliance with this requirement, together with related supporting documentation.

The supporting documentation shall include an indication of the measurement frequency. AOX shall only be measured in processes where chlorine compounds are used for the bleaching of the pulp.

Measurements shall be taken on unfiltered and unsettled samples either after treatment at the plant or after treatment by a public treatment plant.

The measurement period shall be 12 months of production. Measurements shall be taken on a monthly basis from representative composite samples (24 hours composite).

For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. The measurement shall be representative of the respective campaign.

2.3. *Optical brighteners and colouring agents*

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the pulp.
Assessment and verification:

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled.

2.4. *Emission of COD and phosphorous (P) to water and sulphur (S) compounds and NOx to air from production*

The emissions to air and water from the pulp production shall be expressed in terms of points (P_{COD}, P_P, P_S, P_{NOx}). Points are calculated by dividing actual emission by the reference values reported in Table 1.

— None of the individual points P_{COD}, P_P, P_S, P_{NOx}, shall exceed 1,5.

— The total number of points ($P_{total} = P_{COD} + P_P + P_S + P_{NOx}$) shall not exceed 4,0.

For each pulp 'i' sourced, the related measured emissions (expressed in kg/air dried tonne — ADT) shall be weighted according to the proportion of pulp sourced (pulp 'i' with respect to air dried tonne of pulp) and summed together. The reference values for each pulp type used and for the paper production are given in the Table 1. Finally, the total emissions shall be divided by the total reference value as shown in the following formula for COD:

$$P_{COD} = \frac{COD_{total}}{COD_{ref,total}} = \frac{\sum_{i=1}^{n}[pulp_i \times COD_{pulp,i}]}{\sum_{i=1}^{n}[pulp_i \times COD_{ref,pulp,i}]}$$

TABLE 1

Reference values for emissions from different pulp types

Pulp grade	Reference values (kg/ADT)			
	COD_{ref}	P_{ref}	S_{ref}	NOx_{ref}
Bleached chemical pulp (others than sulphite)	18,0	0,045[a]	0,6	1,6
Bleached chemical pulp (sulphite)	25,0	0,045	0,6	1,6
CTMP	15,0	0,01	0,2	0,3

a Net emissions of P are considered in the calculation. The P naturally contained in wood raw materials and in water can be subtracted from the total emissions of P. Reductions up to 0,010 kg/ADT shall be accepted.

In case of a co-generation of heat and electricity at the same plant, the emissions of S and NOx resulting from electricity generation shall be subtracted from the total amount. The following equation shall be used to calculate the proportion of the emissions resulting from heat generation: [MWh(heat) — $MWh(heat)_{sold}$]/[MWh(heat) + 2 × MWh(electricity)]

Where,

— MWh(electricity) is the electricity produced at the co-generation plant,

— MWh(heat) is the useful heat produced in a cogeneration process,

— $MWh(heat)_{sold}$ is the useful heat that is used outside the pulp manufacturing plant.

Assessment and verification:

The applicant shall provide detailed calculations showing compliance with this criterion, together with related supporting documentation which shall include test reports using the following test methods:

— COD: ISO 6060, EPA SM 5220D or HACH 8000,
— P: ISO 6878, SM4500, APAT IRSA CNR 4110 or Dr Lange LCK 349,
— S(oxid.): EPA 8 or equivalent,
— S(red.): EPA 8, EPA 16A or equivalent,
— S content in oil: ISO 8754 or EPA 8,
— S content in coal: ISO 351 or EPA 8,
— NOx: ISO 11564 or EPA 7E.

The supporting documentation shall include an indication of the measurement frequency and the calculation of the points for COD, P, S and NOx. It shall include all emissions of S and NOx which occur during the production of pulp, including steam generated outside the production site, except those emissions related to the production of electricity.

Measurements shall include recovery boilers, lime kilns, steam boilers and destructor furnaces for strong smelling gases. Diffuse emissions shall be taken into account.

Reported emission values for S to air shall include both oxidised and reduced S emissions (dimethyl sulphide, methyl mercaptan, hydrogen sulphide and similar emissions). The S emissions related to the heat energy generation from oil, coal and other external fuels with known S content may be calculated instead of measured, and shall be taken into account.

Measurements of emissions to water shall be taken on unfiltered and unsettled samples either after treatment at the plant or after treatment by a public treatment plant.

The measurement period shall be 12 months of production. Measurements for COD and P shall be taken on a monthly basis and measurements for S and NO_x on a yearly basis. Alternatively, continuous measurements can be accepted if they are verified by a third party at least once per year.

For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. The measurement shall be representative of the respective campaign.

2.5. *Emissions of CO_2 from production*

CO_2 emissions from non-renewable energy sources shall not exceed 450 kg per tonne of pulp produced, including emissions from the production of electricity (whether on-site or off-site). Reference emission values according to Table 2 shall be used in the calculation of CO_2 emission from fuels.

TABLE 2

Reference values for CO_2 emissions from different energy sources

Fuel	**CO_2 fossil emissions**	**Unit**
Coal	95	g $CO_{2\ fossil}$/MJ
Crude oil	73	g $CO_{2\ fossil}$/MJ
Fuel oil 1	74	g $CO_{2\ fossil}$/MJ
Fuel oil 2-5	77	g $CO_{2\ fossil}$/MJ

LPG	69	g $CO_{2\ fossil}$/MJ
Natural Gas	56	g $CO_{2\ fossil}$/MJ
Grid Electricity	400	g $CO_{2\ fossil}$/kWh

Assessment and verification:

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

The applicant shall provide data on the air emissions of carbon dioxide. This shall include all sources of non-renewable fuels during the production of pulp, including the emissions from the production of electricity (whether on-site or off-site).

The measurement period shall be 12 months of production. Measurements shall be done on a yearly basis.

For a new or rebuilt plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. Results have to be shown also after 12 months of production. The measurement shall be representative of the respective campaign.

The amount of energy from renewable sources[(3)] purchased and used for the production processes will not be considered in the calculation of the CO_2 emissions: appropriate documentation that this kind of energy are actually used at the mill or are externally purchased shall be provided by the applicant.

Criterion 3. Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

3.1. *Sourcing*

(a) All pulp fibres shall be covered by valid chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

A minimum of 25 % pulp fibres shall be covered by valid Sustainable Forestry Management certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

The remaining proportion of pulp fibres shall be covered by a verification system which ensures that it is legally sourced and meets any other requirement of the certification scheme with respect to uncertified material.

The certification bodies issuing forest and/or chain of custody certificates shall be accredited/recognised by that certification scheme.

(b) Dissolving pulp produced from cotton linters shall meet the criterion 4.1 for cotton (sourcing and traceability).

Assessment and verification:

(a) The applicant shall obtain from the pulp manufacturer(s) valid, independently certified chain of custody certificates demonstrating that wood fibres have been grown according to Sustainable Forestry Management principles and/or are from legal and controlled sources. FSC, PEFC or equivalent schemes shall be accepted as independent third party certification.

(b) The application shall provide evidence of compliance according to criterion 4.1 for cotton (sourcing and traceability).

3.2. *Bleaching*

The pulp used to manufacture fibres shall not be bleached with the use of chlorine gas. The resulting total amount of adsorbable organically bound halogens (AOX) and organically bound chlorine (OCl) shall not exceed either of the following:

— 0,170 kg/ADT, if measured in the wastewater from pulp manufacturing (AOX), or

— 150 ppm, if measured in the finished fibres (OCl).

Assessment and verification:

The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report showing compliance with either the AOX or the OCl requirement, using the appropriate test method:

— ISO 9562 or the equivalent EPA 1650C for AOX,

— ISO 11480 for OCl.

Frequency of measurement for AOX shall be set in accordance with the criterion 2.2 for fluff pulp.

3.3. *Optical brighteners and colouring agents*

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the fibres.

Assessment and verification:

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled.

3.4. *Production of fibres*

(a) More than 50 % of pulp used to manufacture fibres shall be obtained from dissolving pulp mills that recover value from their spent process liquor either by:

— generating on-site electricity and steam, or

— manufacturing chemical co-products.

(b) The following limit values for the emission of sulphur compounds to air shall be respected in the viscose and in the modal fibres production process:

Table 3

Viscose and modal fibres sulphur emission values

Fibre type	**Sulphur emissions to air — Limit value (g/kg)**
Staple fibre	30
Filament fibre	
— Batch washing	40
— Integrated washing	170

Note: Limit values expressed as annual average.

Assessment and verification:

(a) The applicant shall make the fibres manufacturers to provide a list of pulp suppliers used to produce the fibres and the proportion they supply. Supporting documentation and evidence shall be provided that the required proportion of suppliers has the appropriate energy generating equipment or co-product recovery and manufacturing systems installed at related production sites.

(b) The applicant shall provide detailed documentation and test reports showing compliance with this criterion, together with a declaration of compliance.

Criterion 4. Cotton and other natural cellulosic seed fibres

4.1. *Sourcing and traceability*

(a) Cotton shall be grown according to the requirements laid down in Council Regulation (EC) No 834/2007[(4)], 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 grown according to criterion 4.1(a) and used to manufacture absorbent hygiene product shall be traceable from the point of verification of the production standard.

Assessment and verification:

(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 demonstrate compliance with the cotton content requirement for the annual volume of cotton purchased to manufacture the final product(s) and according to each product line on an annualised basis: Transaction records or invoices shall be provided that document the quantity of cotton purchased on an annual basis from farmers or producer groups, and the total weight of certified bales.

4.2. *Bleaching*

Cotton shall not be bleached with the use of chlorine gas.

Assessment and verification:

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

4.3. *Optical brighteners and colouring agents*

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the cotton.

Assessment and verification:

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled.

Criterion 5. Plastic materials and superabsorbent polymers

5.1. *Production of synthetic polymers and plastic materials*

All plants producing synthetic polymers and plastic materials used in the product shall have implemented systems for:

— 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 of the steam generated during the manufacture of SAPs).

Assessment and verification:

The applicant shall provide a declaration of compliance with the requirement from the suppliers. 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.

5.2. *Additives in plastic materials*

(a) Contents of lead, cadmium, hexavalent chrome and related compounds shall be lower than 0,01 % (100 ppm) of the mass of each plastic material and synthetic polymer used in the product.

(b) Additives used in plastics in concentration above 0,10 % 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[(5)]:

— 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),

— toxic to specific target organs (STOT), category 1: (H370, H372),

— hazardous to the aquatic environment, categories 1 and 2 (H400, H410, H411).

Assessment and verification:

(a), (b) The applicant shall provide a declaration of compliance with the requirements from the suppliers. A list of added substances shall be also provided, including concentrations and related H statements/R phrases, supported by safety data sheets.

In order to facilitate follow-up and monitoring of the documentation provided, a random sample of suppliers may be examined. The supplier shall provide access to production facilities, warehouses and similar installations. Confidentiality applies to any documentation and information submitted and shared.

5.3. *Superabsorbent polymers*

(a) Acrylamide (CAS number: 79-06-1) shall not be intentionally added to the product.

(b) Superabsorbent polymers used in the product may contain a maximum of 1 000 ppm residual monomers that are classified with the H-statements reported in criterion 7 on excluded or limited substances or mixtures. For sodium polyacrilate these represent total of unreacted acrylic acid and cross linkers.

(c) Superabsorbent polymers used in the product may, as a maximum, contain 10 % (weight/weight) of water-soluble extracts and these shall comply with criterion 7 on excluded or limited substances or mixtures. For sodium polyacrilate these represent monomers and oligomers of acrylic acid with lower molecular weight than the superabsorbent polymer according to ISO 17190.

Assessment and verification:

(a) The applicant shall provide a declaration of non-use of the substance.

(b) The applicant shall provide a declaration from the supplier documenting the composition of the super absorbent polymer(s) used in the product. This shall be done by means of product safety data sheets which specify the full name and CAS number and the residual monomers contained in the product classified in accordance with the requirement and the quantities thereof. Recommended test methods are ISO 17190 and WSP 210. The methods used for the analyses shall be described and the names of the laboratories used for analysis shall be stated.

(c) The applicant shall provide a declaration from the supplier specifying the quantity of water-soluble extracts in the superabsorbent polymer(s). Recommended test methods are ISO 17190 and WSP 270. The methods used for the analyses shall be described and the analysis laboratories shall be stated.

Criterion 6. Other materials and components

6.1. *Adhesive materials*

Adhesive materials shall not contain any of the following substances:

— Colophony resins (CAS numbers 8050-09-7, 8052-10-6, 73138-82-6),

— Diisobutyl phthalate (DIBP, CAS number 84-69-5),

— Diisononyl phthalate (DINP, CAS number 28553-12-0),

— Formaldehyde (CAS number 50-00-0).

This requirement shall not apply if those substances are not intentionally added to the material or to the final product, and are present in the adhesive materials in concentrations below 100 ppm (0,010 % by weight).

For formaldehyde, the maximum limit for the content of formaldehyde generated during adhesive production shall be 250 ppm, measured in newly produced polymer dispersion. Content of free formaldehyde in hardened adhesive (glue) shall not exceed 10 ppm. Hotmelt adhesives shall be exempted from this requirement.

Assessment and verification:

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled. Safety data sheets may be used as proof. Test results for formaldehyde shall be provided, with the exception of hotmelt adhesives.

6.2. *Inks and dyes*

The product and any homogeneous part of it shall not be dyed. Derogations to this requirement shall apply to:

— tampon strings, packaging materials and tapes,

— titanium dioxide in polymers and viscose,

— materials that are not directly in contact with the skin may be dyed if the dye fulfils specific functions (e.g. reducing visibility of the product through white or light coloured clothing, showing landing zones of tapes, indicating the wetness).

Inks and dyes used shall also comply with Criterion 7 on excluded or limited substances or mixtures.

Assessment and verification:

The applicant shall provide and shall make suppliers to provide a declaration that the requirements have been fulfilled. In case dyes are used, their presence shall be justified by indicating the specific function provided.

6.3. *Fragrances*

(a) Products marketed as designed and intended for children as well tampons and nursing pads shall be fragrance-free.

(b) Any ingoing substance or mixture added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on IFRA website: http://www.ifraorg.org. The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

(c) Any fragrance used shall also comply with Criterion 7 on excluded or limited substances or mixtures regardless of the concentration in the final product.

(d) Fragrances and ingredients of the fragrance mixtures that are identified as established contact allergens of special concern by the Scientific Committee on Consumer Safety[(6)] as well as the fragrances whose presence, in accordance with Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council[(7)], is required to be indicated in the list of ingredients shall not be used. Further the use of nitromusks and polycyclic musks is not allowed.

(e) The use of fragrances shall be indicated on the product packaging. Further, fragrances and/or ingredients of the fragrance mixtures that are identified as established contact allergens in humans by the Scientific Committee on Consumer and are not restricted by Criterion 6.3 (c) and (d) shall additionally be named.

Assessment and verification:

The applicant shall provide a declaration of compliance for all the requirements laid down in points (a) to (e), supported by a declaration of the fragrance manufacturer, if appropriate. The list of fragrances used and visual evidence that information has been added to the packaging shall be also provided, when fragrances are used.

6.4. *Lotions*

(a) Lotions shall not be used in feminine care pads, tampons and nursing pads. The use of lotions in other products shall be indicated on the packaging.

(b) Any lotion used in products other than feminine care pads, tampons and nursing pads shall comply with Criterion 6.3 on fragrances and Criterion 7 on excluded or limited substances or mixtures regardless of their concentration in the final product.

(c) The following substances shall not be used: triclosan, parabens, formaldehyde and formaldehyde releasers.

Assessment and verification:

The applicant shall provide a declaration of compliance supported by a declaration of the lotion manufacturer, if appropriate. Visual evidence that information has been added to the packaging shall be also provided, when lotions are used.

6.5. *Silicone*

(a) Where components of the product are treated with silicone, the manufacturer shall ensure that employees are protected from the solvents.

(b) Neither octamethyl cyclotetrasiloxane D4 (CAS 556-67-2) nor decamethyl cyclopentasiloxane D5 (CAS 541-02-6) shall be present in chemical products used in the silicone treatment of components. This requirement shall not apply where D4 and

D5 are not intentionally added to the material or to the final product, and where D4 and D5 are present in the silicone in concentrations below 100 ppm (0,01 % by weight).

Assessment and verification:

(a) The applicant shall provide information on the method used for the treatment of silicone and documentation attesting that employees are protected.

(b) The applicant shall provide a declaration from the supplier that this requirement has been fulfilled.

6.6. *Nanosilver particles*

Nanosilver particles shall not be intentionally added to the product or to any homogeneous part or material of it.

Assessment and verification

The applicant shall provide a declaration and shall make suppliers to provide a declaration that this requirement has been fulfilled.

Criterion 7. Excluded or limited substances or mixtures

7.1. *Hazardous substances and mixtures*

The EU Ecolabel may not be awarded if the product or any article of it, as defined in Article 3(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[8], or any homogenous part of it contain substances or mixtures meeting the criteria for classification with the hazard statements or risk phrases specified in table 4, in accordance with Regulation (EC) No 1272/2008 or Council Directive 67/548/EEC[9], nor they contain substances or mixtures referred to in Article 57 of Regulation (EC) No 1907/2006, unless they have been specifically derogated from.

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

The hazard statements and the risk phrases in table 4 generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures shall apply.

Substances or mixtures which change their properties through processing and thus become no longer bioavailable or undergo chemical modification in a way that removes the previously identified hazard are exempted from criterion 7.1. This shall include, for instance, modified polymers and monomers or additives, which become covalently bonded within plastics.

Concentration limits for substances or mixtures which may be or have been assigned the hazard statements or risk phrase listed in table 4, meeting the criteria for classification in the hazard classes or categories, and for substances meeting the criteria of Article 57 (a), (b) or (c) of Regulation (EC) No 1907/2006, shall not exceed the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008. Where specific concentration limits are determined they shall prevail over the generic ones.

TABLE 4

Hazard statements and respective risk phrases

Hazard Statement[a]	**Risk Phrase**[b]
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22

Notes

a In accordance with Regulation (EC) No 1272/2008.

b In accordance with Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1).

c In accordance with Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 83, 30.3.2011, p. 1).

H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
H317 (Sub-category 1A): May cause allergic skin reaction (trigger concentration ≥ 0,1 % w/w)[c]	R43
H317 (Sub-category 1B): May cause allergic skin reaction (trigger concentration ≥ 1,0 % w/w)[c]	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42

Notes

a In accordance with Regulation (EC) No 1272/2008.

b In accordance with Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1).

c In accordance with Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 83, 30.3.2011, p. 1).

Assessment and verification:

The applicant shall provide the bill of materials of the product, including a list with all articles and homogeneous part of it.

The applicant shall screen the presence of substances and mixtures that may be classified with the hazard statements or risk phrases reported in this criterion. The applicant shall provide a

declaration of compliance with this criterion for the product, any article of it or any homogenous part of it.

Applicants shall select the appropriate forms of verification. The main forms of verification are set out as follows:

— homogenous parts and any associated treatments or impurities (e.g. superabsorbent polymer layer): safety data sheets shall be provided for the materials composing that part of product and for substances and mixtures used in the formulation and treatment of the materials remaining in the final part above a cut-off limit of 0,10 % w/w unless a lower generic or specific concentration limit applies in accordance with the Article 10 of Regulation (EC) No 1272/2008,

— chemical recipes used to impart a specific function to the product or to components of the product (e.g. glues and adhesives, dyes): safety data sheets shall be provided for substances and mixtures used in the assembly of the final product or substances and mixtures applied to components of the product and remaining in the components of the product.

That declaration shall include related documentation, such as declarations of compliance signed by the suppliers, on the non-classification of the substances, mixtures or materials with any of the hazard classes associated to the hazard statements or risk phrases referred in table 4 in accordance with Regulation (EC) No 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII to Regulation (EC) No 1907/2006.

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

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

(i) 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;

(ii) 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;

(iii) 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 substances hazard classification in accordance with Annex II to Regulation (EC) No 1907/2006;

(iv) 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.

Safety data sheets (SDS) shall be completed in accordance with the guidance set out in Section 2, 3, 9, 10, 11 and 12 of Annex II to Regulation (EC) No 1907/2006 (requirements for the compilation of safety data sheets). Incomplete SDS shall require supplementing with information from declarations by chemical suppliers.

Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as in vitro methods, by quantitative

structure activity models or by the use of grouping or read-across in accordance with Annex XI to Regulation (EC) No 1907/2006. The sharing of relevant data across the supply chain is strongly encouraged.

7.2. *Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006*

No derogation from the exclusion in Article 6(6) of Regulation (EC) No 66/2010 shall be given concerning substances identified as substances of very high concern and included in the list provided for in Article 59(1) of Regulation (EC) No 1907/2006, present in mixtures, in an article or in any homogeneous part of the product in concentrations > 0,10 % by weight.
Assessment and verification

Reference to the latest list of substances of very high concern shall be made on the date of application. The applicant shall provide a declaration of compliance with criterion 7.2, together with related documentation, including declarations of compliance signed by the material suppliers and copies of relevant SDS for substances or mixtures in accordance with Annex II to Regulation (EC) No 1907/2006 for substances or mixtures. Concentration limits shall be specified in the safety data sheets in accordance with Article 31 of Regulation (EC) No 1907/2006 for substances and mixtures.

Criterion 8. Material efficiency in the manufacturing

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

— 10 % by weight of the end products for tampons,

— 5 % by weight of the end products for all the other 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 9. Guidance on the product disposal

The producers shall write or indicate through visual symbols on the packaging:

— that the product must not be flushed into toilets,

— how to dispose the product correctly.

Assessment and verification:

The applicant shall provide a sample of the packaging.

Criterion 10. Fitness for use and quality of the product

The efficiency/quality of the product shall be satisfactory and at the least equivalent of products 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.

TABLE 5

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

Characteristic			**Testing practice required (performance threshold)**			
			Baby diapers	**Feminine care pads**	**Tampons**	**Nursing pads**
In-use tests	U1.	Absorption and leakage protection[a]	Consumer panel test (Leakage occurs in less than 5 % of the product uses)			
	U2.	Skin dryness	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)		Not applicable	As for baby diapers
	U3.	Fit and comfort	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U4.	Overall performance	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
Technical tests	T1.	Absorption and leakage protection	Absorption rate and absorption before leakage		Syngina method	No method recommended
	T2.	Skin dryness	TEWL, rewet method or corneometric testing		Not applicable	No method recommended

a Panty liners without a core intended to protect the feminine lingerie (light panty liners) are derogated from this requirement.

Assessment and verification:

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

Tests shall be conducted for the specific type and size of 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. Special care shall be taken regarding sampling, transport and storage of the 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.

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.

— When the product is not designed specifically for a single gender, the ratio of male to female individuals shall be 1:1.

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

— Sick individuals and those with a chronic skin 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 skin dryness, 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). For absorption and leakage protection, leakage shall occur in less than 5 % of the products tested.

— 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.

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.

Weight, dimensions and design features of the product shall be described and provided in accordance with criterion 1.

Criterion 11. Social aspects

Applicants shall ensure that the fundamental principles and rights at work as described in the International Labour Organisation's (ILO) Core Labour Standards, the UN Global Compact and the OECD Guidelines for Multi-National Enterprises shall be observed by production sites along the supply chain used to manufacture the licensed product(s). For the purpose of verification, the following ILO Core Labour Standards shall be referred to:

029	Forced Labour
087	Freedom of Association and Protection of the Right to Organise
098	Right to Organise and Collective Bargaining
100	Equal remuneration
105	Abolition of Forced Labour

111	Discrimination (Employment and Occupation)
138	Minimum Age Convention
155	Occupational safety and health
182	Elimination of the Worst Forms of Child Labour

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

Assessment and verification

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. This shall take place upon application and subsequently during the license period if new production sites are introduced.

Criterion 12. Information appearing on the EU Ecolabel

The EU Ecolabel logo shall be applied on the packaging of the product. Box 2 of the EU Ecolabel shall contain the following text:

— ‘Reduced impacts from consumption of resources’,

— ‘Restricted use of hazardous substances’,

— ‘Performance and quality tests satisfied’.

The following text should moreover appear on the packaging: ‘For more information on why this product has been awarded the EU Ecolabel, please visit http://ec.europa.eu/environment/ecolabel/’.

Assessment and verification

The applicant shall provide a declaration of compliance with the requirement and visual evidence.

(**1**) OJ L 27, 30.1.2010, p. 1.

(**2**) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(**3**) As defined in Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

(**4**) Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

(**5**) 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).

(**6**) SCCS Opinion on Fragrance allergens in cosmetic products adopted in June 2012 http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

(**7**) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

(**8**) 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).

(**9**) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).