

## **PERSONAL CARE AND COSMETIC PRODUCT GROUP ENVIRONMENTAL LABEL CRITERIA**

**Article 1** - These criteria are regulated within the scope of the 9th and 15th articles of the Environmental Label Regulation published in the Official Gazette dated 19/10/2018 and numbered 30570.

**Article 2** - These criteria include solid soap, liquid soap, shampoo, shower gel, hand and body cream, hair cream, shaving soap, and shaving foam products.

In our country, sustainable production and consumption practices are supported with the national environmental label criteria determined for the personal care and cosmetic products such as solid soap, liquid soap, shampoo, shower gel, hand and body cream, hair cream, shaving soap, and shaving foam that produced, distributed, exported, or put on the market through import.

The criteria do not cover products used for disinfectant and antibacterial purposes.

**Article 3** - For the products included in Article 2 within the scope of personal care and cosmetics product group to be given an environmental label, the criteria specified in this document must be fulfilled.

**Article 4** - (1) In terms of the application of the criteria, the following definitions are valid in addition to the definitions in the Environmental Label Regulation published in the Official Gazette dated 19/10/2018 and numbered 30570 within the scope of personal care and cosmetic products:

- a) Active ingredient: Active ingredient: It refers to the total of organic input materials in the product formulation and expressed in grams.
- b) Primary packaging: It refers to the packaging that is in direct contact with the content designed to form the smallest sales unit to the end-user or consumer at the point of purchase.
- c) Secondary packaging: It refers to the packaging that can be separated from the product without affecting the character of the product, designed to form a grouping of a certain number of products and sold to the end-user as such, or used only to fill the shelves at the point of sale.
- d) INCI: It is the abbreviation of the words "International Nomenclature Cosmetic Ingredients"; refers to the international cosmetic product ingredient nomenclature.
- e) Critical dilution volume: It refers to the natural volume of water required to dilute the effect of a product on aquatic freshwater ecosystems, an amount of the product (or functional unit) to a concentration where it does not cause any foreseeable harmful effects on water and an amount of the product (or functional unit).
- f) Preservatives: It refers to the substances that are used alone or in combination intended to inhibit the development of microorganisms in the cosmetic product.
- g) Cosmetic Product: It refers to all substances or mixtures prepared for external parts of the human body; be applied to the epidermis, nails, hairs, hair, lips, and external genitalia, or

to the teeth and oral mucosa, whose sole or primary purpose is to clean, scent, change their appearance, protect them, keep them in good condition or correct body odors.

**Article 5** - The evaluation and verification requirements regarding the Environmental Label criteria determined for the " Personal Care and Cosmetic Products " will be valid for 5 (five) years from the date of publication. The criteria may be updated within five years when deemed necessary by the Environmental Labeling Board. The validity period of the criteria can be extended based on the approval of the Environmental Labeling Board.

**Article 6** - In order to assess and verify the conformity of the products to the environmental label criteria, it is necessary to submit the necessary measurement and test methods and confirmatory documents in the first part of this document.

Under the protocol signed between the Ministry and the Turkish Standards Institute (TSI), TSI has the authority to determine a technical inspection commission to evaluate the environmental label applications by examining and verifying the compliance of the applications with the criteria, to prepare a technical report and to inspect the compliance of the environmental label with the criteria.

## **I. Assessment and Verification Requirements**

### **a. Requirements**

The specific assessment and verification requirements are indicated within each criterion.

The applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, it is understood that these may originate from the applicant and/or his supplier(s) and/or their supplier(s), et cetera, as appropriate.

A method different from the test methods determined for each criterion can be used by evaluating on a case-by-case basis, provided that the equivalence is accepted by the technical evaluation committee.

The Ministry recognizes the tests performed by laboratories accredited by an accreditation body that is a party to the International Laboratory Accreditation Cooperation (ILAC) - Mutual Recognition Agreement (MRA) according to TS EN ISO/IEC 17025. TÜRKAK accredited organizations can be accessed at <https://secure.turkak.org.tr/kapsam/search>. TS EN ISO/IEC 17025 accreditation condition is not required if it is documented that there is no accredited organization for the test method, which is mandatory within the scope of assessment and verification requirements. If deemed appropriate, the Ministry/TSI may request supporting documents and perform independent verification.

When generating data on the classification of substances or mixtures, the provisions of the "Regulation on the Test Methods to be Applied in Determining the Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures" in the Official Gazette dated 11.12.2013 and numbered 28848 with the second duplicate, or with internationally recognized scientific principles or validated methods under international procedures shall be considered.

The applicant shall have fulfilled the necessary obligations within the scope of the Product Safety and Technical Regulations Law No. 7223, as well as the Environmental Law and the current legislation enacted based on this law. In this respect, it is obliged to submit the Environmental Impact Assessment (EIA) Decision, Environmental Permit, Zero Waste Certificate, Waste Management Plan, and other documents requested by the Ministry.

It is necessary to demonstrate the toxicity and biodegradability effects of the chemicals and mixtures used in personal care and cosmetics products on aquatic environments. For this, the "EU Commission Detergent Content Database" (Detergent Ingredient Database - DID list)<sup>1</sup> has been developed and includes the most used substances in detergent and cosmetic formulations. This list will be used to derive the necessary data for calculations of the Critical Dilution Volume (CDV) and to evaluate the biodegradability of the substances used in the product.

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<sup>1</sup> [http://ec.europa.eu/environment/ecolabel/documents/did\\_list/didlist\\_part\\_a\\_en.pdf](http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf)  
[http://ec.europa.eu/environment/ecolabel/documents/did\\_list/didlist\\_part\\_b\\_en.pdf](http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf)

In addition, the following information about the product or products applied for will be provided to the Ministry by the applicant:

- (i) Presenting the prescription of the product clearly and understandably that the verifier can understand, indicating the trade name, chemical name, CAS No and INCI (International Nomenclature Cosmetic Ingredient) definitions, DID No<sup>2</sup>, input amount including and without water, the function and chemical structure of all components regardless of concentration, and in the process, the maximum values declared by the company will be used for calculations.
- (ii) Under the "Regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals" published in the Official Gazette dated 23.06.2017 and secondly numbered 30105, Safety Data Sheet (SDS) will be provided for each input substance or mixture. If SDS is not available for each substance that is a component of a mixture, the applicant shall provide the SDS of the mixture.

As stated in Article 6 of the "Guideline on the Analysis of Cosmetic Products" published by Ministry of Health, Turkish Medicines and Medical Devices Agency, TS EN ISO/IEC 17025 standard, TS 5822-1 ISO 5725-1, TS 5822-2 ISO 5725-2, TS 5822-3 ISO 5725-3, TS 5822-4 ISO 5725-4, TS 5822-5 ISO 5725-5 and TS 5822-6 ISO 5725-6 standards (standards for accuracy of measurement methods and results, 6 chapters) or related IUPAC guidelines for the validation of the methods, which allows the control of whether the product complies with the 7th article of the Cosmetics Regulation for conformity control can be used for analysis methods.

In accordance with the 12th Article of the Cosmetics Regulation No. 25823 dated 23.05.2005 published in the Official Gazette, the "Cosmetic Product Safety Report", which states that the product is safe, must be prepared by appropriate persons before a cosmetic product is placed on the market. A person who has a diploma in pharmacy or has a certificate given to those who have completed the theoretical and applied curriculum offered in the field of toxicology or cosmetic product safety assessment with a diploma in medicine, dentistry, biology, chemistry, biochemistry, microbiology, or equivalent is qualified to prepare a safety report.

In Annex I/B part of this regulation, there is information that the products shall contain at least in terms of physical, chemical, and microbiological properties. It is expected that the Cosmetic Product Safety Report will contain the information necessary for compliance with the criteria.

If the validity date of the test or measurement findings made for items that have completed all processes and are on sale is deemed appropriate to be accepted with the application for the Environmental Label, the measurements and/or tests whose validity date has expired must be performed again.

With the application for the Environmental Label application, if the validity date of the test or measurement results made for the products that have completed all the processes and are on sale, it is deemed appropriate to be accepted, and the measurements and/or tests whose validity date has expired must be performed again.

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<sup>2</sup> DID No is the number of the input chemical in the DID list

## **b. Measurement Thresholds**

Compliance with the defined criteria is required for all ingoing substances determined for the personal care and cosmetic products group. The “Excluded and Restricted Substances” criterion is equal to or exceeds 0.01% by weight in the final formulation for fragrance agents, preservatives, and coloring agents in item (b) and items (c), (d), (e), respectively. Cases, compliance with the criteria is sought.

## **II. Environmental Label Criteria**

### **Criterion 1. Sustainable Sourcing of Palm Oil, Palm Kernel Oil, and Their Derivatives**

Ingoing substances used in the products which are derived from palm oil or palm kernel oil shall be sourced from plantations that meet the requirements of a certification scheme for sustainable production that is based on multistakeholder organizations that has a broad membership.

**Assessment and verification:** The applicant shall provide evidence through third-party certificates and chain of custody that palm oil and palm kernel oil used in the manufacturing of the ingoing substances originates from sustainably managed plantations.

In order to prove that products containing palm oil, palm kernel oil, and their derivatives are obtained with sustainable management, the applicant or suppliers RSPO (Sustainable Palm Oil Roundtable) (palm oil with a certain product type, separated or produced by mass balance) or based on the criteria of multi-stakeholder sustainable management must have certificates such as GreenPalm RSB (Roundtable on Sustainable Biomaterials), ISCC (International Sustainable Palm Oil), MSPO (Malaysian Sustainable Palm Oil) and/or ISPO (Indonesian Sustainable Palm Oil).

If the applicant has a certificate other than these certificates, the applicant shall prove its validity by comparing its criteria with RSPO.

### **Criterion 2. Biodegradability**

#### **(a) Biodegradability of Surfactants**

All surfactants shall be readily biodegradable under aerobic conditions and biodegradable under anaerobic conditions.

#### **(b) Biodegradability of Organic Compounds**

The content of all organic ingoing substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) or anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 1.

$$a\text{NBO} = \sum a\text{NBO}(i) \text{ (amount of organic compound in reference dose, g)}$$

When organic compounds are readily biodegradable (R),  $a\text{NBO}(i) = 0$  When organic compounds are inherently biodegradable (I),  $a\text{NBO}(i) = 0$

$$\text{anNBO} = \sum \text{anNBO}(i) \text{ (amount of organic compound in reference dose, g)}$$

When organic compounds biodegrade anaerobically (Y),  $\text{anNBO}(i) = 0$

**Table 1:** aNBO and anNBO limits

Product Type	aNBO (mg/g AC <sup>3</sup> )	anNBO (mg/g AC)
Shampoos, shower gels, and liquid soaps	25	25
Solid soaps	10	10
Hair conditioners	45	45
Shaving foams*	70	40
Shaving soaps	10	10

\*Shaving foams include shaving gels and shaving creams.

**Assessment and verification:** The applicant shall provide documentation for the degradability of surfactants, as well as the calculation of aNBO and anNBO for the product. For the degradability of surfactants and the aNBO and anNBO values of organic compounds, reference shall be made to the most recent DID list.

For both the degradability of surfactants and the aNBO and anNBO values for organic compounds, reference shall be made to the most updated DID list.

If the ingoing substances are not included in this list, aNBO and anNBO values shall be calculated using OECD 311, OECD 301 A, OECD 301 B, TS EN ISO 9439 OECD 301 C, OECD 301 D, TS ISO 10708 OECD 301 E, OECD 301 F, TS EN ISO 9408, OECD 302 A, OECD 302 B, OECD 302 C and TS EN ISO 9887 test results showing that they are biodegradable aerobically and anaerobically, and the test results shall be presented in the documentation. For surfactants not included in this list, with the approval of the technical evaluation commission, information from literature or other sources showing that they are biodegradable aerobically and anaerobically can be obtained.

For surfactants not included in this list, based on the approval of the technical review commission, information from the literature or other sources showing that they are biodegradable aerobically and anaerobically can be obtained.

As stated in the 3rd paragraph of Article 5 of the "Regulation on the Test Methods to be Applied in the Determination of the Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures" published by the Ministry of Environment, Urbanization and Climate Change in the Official Gazette dated 11.12.2013 and with the second duplicate number 28848, related test methods such as C.4-C, C.4-D, C.4-E, C.4-F included in Annex I/C section of the Regulation can also be used to determine the ecotoxicological properties of substances and mixtures arising from their intrinsic properties. For adsorption and desorption tests, the methods

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<sup>3</sup> AC: Active Content

defined in C.18: Adsorption/Desorption method using the Discrete Equilibrium Model in Annex I/C of the same regulation shall be followed.

The applicant shall provide a declaration stating that the product does not exceed the limit aNBO and anNBO values.

### Criterion 3. Toxicity to the Aquatic Organisms, Critical Dilution Volume (CDV)

The critical dilution volume estimates the impact of a product on aquatic freshwater ecosystems by calculating the natural water volume required to dilute some amount of the product (or functional unit) to the concentration at which it does not cause any foreseeable detrimental effects on the water.

The critical dilution volume of the product ( $CDV_{\text{chronic}}$ ) shall not exceed the following limits for the reference dosage:

**Table 2** CDV Limit Values

Product Type	Limit CDV (L/g AC)
Shampoos, shower gels, and liquid soaps	18 000
Solid soaps	3 300
Hair conditioners	25 000
Shaving foams*	20 000
Shaving soaps	3 300

\*Shaving foams include shaving gels and shaving creams.

$CDV_{\text{chronic}}$  is calculated for all ingredients (i) in the product using the following equation:

$$CDV_{\text{chronic}} = \sum CDV_{(i)} = 1000 * \sum \text{dosage} (i) * \frac{DF(i)}{TF_{\text{chronic}}(i)}$$

Where;

dosage (i): Weight (g) of the substance (i) in the reference dosage,

DF<sub>(i)</sub>: Degradation factor for the substance (i);

TF<sub>chronic (i)</sub>: Chronic toxicity factor for the substance (i).

**Assessment and verification:** The applicant shall provide the calculation of the  $CDV_{\text{chronic}}$  of the product. A spreadsheet for the calculation of the CDV value is available on the EU Ecolabel website. The values of DF and TF chronic shall be as given in the DID list-part A. If the ingoing substance is not included in the DID list-part A, the applicant shall determine the values using the guidelines described in the DID list-part B and attach the associated documentation.

In addition, the "Regulation on the Test Methods to be Applied in the Determination of the Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures" published in the Official Gazette dated 11.12.2013 and with the second duplicate number 28848 by the Ministry of Environment, Urbanization and Climate Change provisions shall be considered.

The applicant shall submit a declaration stating that the product does not exceed the limit CDV values.

#### **Criterion 4. Excluded and restricted substances**

##### **(a) Specified excluded substances**

The following ingredients and mixtures shall not be included in the product formulation or any mixture added to the formulation:

- Alkylphenol ethoxylates (APEOs) and other alkylphenol derivatives;
- Nitrilo-triacetate (NTA);
- Nitro musks and polycyclic musks;
- Octamethylcyclotetrasiloxane (D4);
- Butylated hydroxytoluene (BHT);
- Ethylenediaminetetraacetic acid (EDTA) and its salts;
- Triclosan, parabens, formaldehyde, and formaldehyde sequestrants;
- Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), atranol, and chloroatranol;
- Microplastics and nanosilver.

**Assessment and verification:** The applicant shall submit a signed statement, supported by the statements of the mixture manufacturers shall submit the product prescription with the declaration of conformity that the listed substances and/or mixtures are not included in the product, considering the Cosmetic Regulation No. 25823 dated 23.05.2005 published in the Official Gazette by Ministry of Health.

##### **(b) Hazardous substances**

Acute toxicity, specific target organ toxicity, respiratory or skin sensitizer, in accordance with the list in Table 3, within the scope of Annex-I of the "Regulation on Classification, Labeling and Packaging of Substances and Mixtures" published in the Official Gazette dated 11.12.2013 and with the second repeated number of 28848, Hazard statements are included in the categories harmful to the aquatic environment, carcinogenic, mutagenic or toxic to the reproductive system. Environmental Labels cannot be given to products that correspond to the specified classification of hazard statements or contain substances given in Annex II of the Cosmetics Regulation.

Substances or mixtures which, by processing, change their properties and are therefore no longer bioavailable or which have undergone chemical modification to eliminate the previously identified hazard are exempt from criterion 4(b).



**Table 3** Restricted hazard classifications and their categorization

<b>Acute toxicity</b>	
<b>Categories 1 and 2</b>	<b>Category 3</b>
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
<b>Specific target on organ toxicity</b>	
<b>Category 1</b>	<b>Category 2</b>
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
<b>Respiratory and skin sensitization</b>	
<b>Category 1A/1</b>	<b>Category 1B</b>
H317 May cause an allergic skin reaction	H317 May cause an 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
<b>Hazardous to the aquatic environment</b>	
<b>Categories 1 and 2</b>	<b>Category 3 and 4</b>
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 on aquatic life
H411 Toxic to aquatic life with long-lasting effects	
<b>Hazardous to the ozone layer</b>	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	

Table 4 shows the relevant hazard statements for exceptional substances.

**Table 4** Derogated substances and their hazard statements

<b>Substance</b>	<b>Hazard Statement</b>
Surfactants (concentration less than 20% found in the final product)	H412 Harmful to aquatic life with long-lasting effects
	H413 May cause long-lasting effects on aquatic life
Fragrance Ingredients	H412 Harmful to aquatic life with long-lasting effects
	H413 May cause long-lasting effects on aquatic life
Preservatives	H411 Toxic to aquatic life with long-lasting effects
	H412 Harmful to aquatic life with long-lasting effects
	H413 May cause long-lasting effects on aquatic life
Anti-Dandruff Shampoos Using Zinc Pyrithione (ZPT)	H400 Very toxic to aquatic life

**Assessment and verification:** The applicant must submit a declaration and show a bill of materials stating its compliance with criterion 4(b) for each substance and mixture present in concentrations higher than 0.01% regarding the exceptional substances contained in the product.

In order to control the hazard statements of the substances used in the product, the applicant shall submit a Safety Data Sheet for each substance and a signed declaration stating that the listed substances are not found in the product, provided by the mixture manufacturers.

In terms of acute toxicity, specific target organ toxicity, respiratory and skin damage, damage to the aquatic environment, carcinogenicity, mutagenicity, or toxic effect for the reproductive system of the substances contained in the product obtained after the production stage, it was published in the Official Gazette dated 11.12.2013 by Ministry of Environment, Urbanization and Climate Change. and secondly numbered 28848 "Regulation on the Test Methods to be Applied in Determining the Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures", Article 5, paragraph 2, the test methods specified in the relevant annex of the Regulation shall be taken into consideration.

In accordance with these test methods, OECD Guidelines Part 4 – Health Effects ([https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects\\_20745788? Page=1](https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788? Page=1)) methods may also be considered.

A declaration by the applicant for substances will be sufficient for eligibility for listed within the scope of Annex IV and Annex V of the "Regulation on Registration, Evaluation, Authorization, and Restriction of Chemicals", which entered into force after being published in the Official Gazette dated 23/06/2017 and secondly numbered 30105 and exempted from registration in subparagraphs (a) and (b) of the fifth paragraph of article 2 of the Regulation.

### (c) **Fragrances**

- (i) Any 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).
- (ii) Fragrance substances to be used in products designed and marketed for children (under 3 years of age) shall not exceed the concentrations determined in Appendix III of the Cosmetics Regulation.

**Assessment and verification:** The applicant shall submit a signed statement supported by the fragrance manufacturer's statement. It shall be declared that the substances used for fragrance and included in Appendix III of the Cosmetics Regulation dated 23.05.2005 and numbered 25823 published in the Official Gazette by the Ministry of Health shall not be used in more than the specified limits.

At the same time, the "Regulation on the Test Methods to be Applied in the Determination of the Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures" published in the Official Gazette dated 11.12.2013 and numbered 28848 by the Ministry of Environment, Urbanization and Climate Change, Article 5, the provision of paragraph 2 "*Test methods in the B part of Annex-1 of this Regulation are used in determining the toxicological*

*properties of substances and mixtures arising from their intrinsic properties*" shall be taken into consideration.

In addition, Analytical Methods to Calculate the Amount of 57 Possible Injectable-Ready Allergens (and Their Isomers) in Fragrance Substances by Gas Chromatography and Mass Spectrometry([https://ifrafragrance.org/docs/default-source/guidelines/23754\\_gd\\_2017\\_04\\_11\\_ifra\\_analytical\\_method\\_to\\_quantify\\_57\\_suspected\\_allergens\\_\(and\\_isomers\)\\_in\\_ready\\_to\\_inject\\_fragrance\\_materials\\_by\\_gc-ms-\(3\).pdf?sfvrsn=ad55ac1\\_6](https://ifrafragrance.org/docs/default-source/guidelines/23754_gd_2017_04_11_ifra_analytical_method_to_quantify_57_suspected_allergens_(and_isomers)_in_ready_to_inject_fragrance_materials_by_gc-ms-(3).pdf?sfvrsn=ad55ac1_6)) published by the International Fragrance Association (IFRA) document shall be taken into consideration. The method described in this document enables the identification and measurement of volatile compounds in vitro. The method is performed by GC-MS on "ready-to-inject" matrix samples and is compatible with gas chromatography.

#### **(d) Preservatives**

- (i) The preservatives contained in the product comply with the requirements outlined in criterion 4(b) and do not release or degrade into substances classified as hazardous.
- (ii) If the product does not bioaccumulate, it may contain preservatives. A preservative is considered non-bioaccumulative if the BCF value is less than 100 or the log  $K_{ow}$  value is less than 3.0.

**Assessment and verification:** The biological concentration factor (BCF – bioconcentration factor) is a value used to evaluate the environmental performance of a chemical, such as whether it is bioaccumulative or not. It is calculated as follows:

$$\text{BCF} = \frac{\text{concentration (mg/kg) in the organism (usually fish)}}{\text{concentration in the environment (mg/L)}}$$

As the BCF value of a chemical increases, its solubility in water decreases.

Octanol-water partition coefficient - log  $K_{ow}$  measures the hydrophobic property of a chemical. It is seen as a useful value for evaluating the path a chemical takes after it is released into the environment. It is calculated as follows:

$$\text{Log } K_{ow} = \frac{\text{concentration in octanol}}{\text{concentration in water}}$$

The log  $K_{ow}$  value of a chemical is inversely proportional to its solubility in water and directly proportional to its molecular weight.

The applicant shall submit a declaration stating that the prohibited preservatives specified in criterion 4(b) and Annex V of the Cosmetics Regulation dated 23.05.2005 and numbered 25823 is not used in the product.

The applicant shall submit a declaration stating that the preservatives used in the product formulation do not exceed the limit BCF and log  $K_{ow}$  values. The declaration shall be supported by safety data sheets.

#### **(e) Colorants**

Colorants in products shall not be bioaccumulated. A colorant is considered non-bioaccumulative if its BCF value is less than 100 or its log  $K_{ow}$  value is less than 3.0. If both BCF and log  $K_{ow}$  values are available, the highest measured BCF value is used. For colorants approved for use in foods, documentation showing the potential for bioaccumulation need not be submitted.

**Assessment and verification:** The applicant shall submit a declaration stating that the colorants used in the product formulation do not exceed the limit BCF and log  $K_{ow}$  values. The declaration shall be supported by safety data sheets.

#### **(f) Rinse-off products**

Hand and body creams in the rinse-off product category shall not contain aluminum in their formulation; In addition, heavy metals (lead, arsenic, cadmium, mercury, and antimony) evaluated within the scope of the "Guideline on Heavy Metal Impurities in Cosmetic Products" published by Medicines and Medical Devices Agency of the Ministry of Health shall not exceed the limit values specified for cosmetic products.

**Assessment and verification:** The applicant shall have the heavy metal tests of the product performed in accredited laboratories and prove that the heavy metals within the scope of the "Guideline on Heavy Metal Impurities in Cosmetic Products" in the product formulation do not exceed the limit values (Lead: 20 ppm, Arsenic: 5 ppm, Cadmium: 5 ppm, Mercury: 1 ppm and Antimony: 10 ppm) specified in accordance with Article 11. In addition, it shall present a declaration that there is no aluminum in the product formulation and show the product recipe.

#### **(g) Substances of Very High Concern (SVHC)**

The final product cannot contain substances that have the characteristics of substances of high importance as defined in Article 47 of the Regulation on Registration, Evaluation, Authorization, and Restriction of Chemicals.

**Assessment and verification:** The applicant shall provide a signed declaration of conformity, supported by statements and SDSs from suppliers, confirming the absence of substances of high concern, if applicable.

#### **Criterion 5: Energy Management**

Companies shall have the TS EN ISO 50001 Energy Management System, which is a guide in ensuring the use of renewable energy sources, taking measures to save energy, and realizing regulations for efficient use of energy. Companies that do not have this standardization shall prepare an Energy Management Plan to achieve the objectives specified within the scope of energy management.

**Assessment and verification:** The applicant shall provide the TS EN ISO 50001 Energy Management System standardization, and in this context, they shall present the Energy Management Plan within a system to be prepared by energy experts. The efficiency obtained with the plan shall be demonstrated using the "TS ISO 50015: 2014 Measurement and Verification of

Energy Performance of Organizations" standard and improvement shall be proven. Businesses that already have TS EN ISO 50001 Energy Management System certificates are deemed to have met this criterion.

On the other hand, it is not required for every business to establish an Energy Management System. Applicants who do not have the TS EN ISO 50001 Energy Management System will appoint an energy manager, prepare an energy management plan specific to energy efficiency and production, and monitor their energy consumption. The National Energy Efficiency Action Plan, published in the Official Gazette on 27.10.2011, and numbered 30971, can be used as an example in establishing the Energy Management Plan. In addition, the provisions of the "Regulation on Increasing Efficiency in the Use of Energy Resources and Energy" published in the Official Gazette dated 27.10.2011 and numbered 28097 by the Ministry of Energy and Natural Resources shall be utilized. In addition, the updates within the scope of the "Regulation Amending the Regulation on Increasing Efficiency in the Use of Energy Resources and Energy" published in the Official Gazette dated 25.01.2020 and numbered 31019 shall also be considered.

## **Criterion 6: Packaging**

### **(a) Primary Packaging**

Primary packaging is packaging that is in direct contact with the content. Additional packaging such as cardboard boxes is not allowed for the product offered for sale.

Secondary packaging is not permitted for hand and body creams whose primary packaging is in tube form.

**Assessment and verification:** The applicant shall submit a signed statement that is about the usage of only primary packaging and the reduction of the amount of packaging, unless technically necessary.

The applicant shall submit a declaration that no secondary packaging is used for hand and body creams in which tubes are used as the primary packaging. In case secondary packaging is used, it shall present the mandatory justifications for this use to the technical inspection commission with an explanatory text.

### **(b) Packaging Impact Ratio (PIR)**

The Packaging Impact Ratio (PIR) shall be less than 0,28 g of packaging per gram of product for each of the packaging in which the product is sold. Products packed in metal aerosol containers shall be exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$\text{PIR} = (\text{W} + (\text{W}_{\text{refill}} \times \text{F}) + \text{N} + (\text{N}_{\text{refill}} \times \text{F})) / (\text{D} + (\text{D}_{\text{refill}} \times \text{F}))$$

Where:

W —the weight of packaging (primary + proportion of secondary<sup>4</sup>, including labels) (g)

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<sup>4</sup> Proportional weight of the grouping packaging (e.g. 50 % of the total grouping packaging weight, if two products are sold together).

$W_{\text{refill}}$  —the weight of refill packaging (primary + proportion of secondary, including labels) (g)

$N$  —weight of non-renewable + non-recycled packaging (primary + proportion of secondary, including labels) (g)

$N_{\text{refill}}$  —the weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary, including labels) (g)

$D$  —the weight of product contained in the ‘parent’ pack (g)

$D_{\text{refill}}$  —the weight of product delivered by the refill (g)

F-number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R/V_{\text{refill}}$$

Where:

$V$  —volume capacity of the parent pack (mL)

$V_{\text{refill}}$  —volume capacity of the refill pack (mL)

$R$  —the refillable quantity. This is the number of times that the parent pack can be refilled.

Where  $F$  is not a whole number it shall be rounded up to the next whole number.

In case no refill is offered PIR shall be calculated as follows:

$$\text{PIR} = (W + N)/D$$

The manufacturer shall provide the number of foreseen refillings, or use the default values of

$R = 5$  for plastics and  $R = 2$  for cardboard.

**Assessment and verification:** The applicant shall provide the calculation of the PIR of the product. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the Ecolabel shall be awarded. For the approval of refill packaging, the applicant or retailer shall demonstrate that the refills shall be available for purchase on the market.

### (c) Design of primary packaging

The primary packaging shall be designed in such a way that it is easy to administer the correct dosage (for example, by ensuring that the top opening is not too wide) and that at least 90% of the product is easily emptied from the container. The remaining amount ( $R$ ) of the product in the container after consumer use shall be less than 10% and shall be calculated as follows:

$$R = ((m2 - m3)/(m1 - m3)) \times 100 (\%)$$

Where:

$m1$  — Primary packaging and product (g)

$m2$  — Primary packaging and product residue in normal conditions of use (g)

$m3$  — Primary packaging emptied and cleaned (g)

The discharge level, which shall be 90% for personal care products packaging, is valid for liquid soap, shampoo, hair cream products that require rinsing, as well as for hand and body creams that do not require rinsing and can stay on the skin for a long time.

**Assessment and verification:** If the applicant are applying a refill system, the applicant shall submit a statement describing the system applied. If backfilling is not applied, the applicant shall calculate the amount (R) of the product in the package that remains in the container after consumer use. The applicant shall also submit a final report with calculations for the amount of product remaining in the container. The technical inspection commission can perform an on-site check when necessary.

**(d) Design for recycling of plastic packaging**

Plastic packaging shall be designed to facilitate effective recycling. Table 5 lists the materials and components that shall not be present in packaging equipment. Pumps and aerosol containers are exempt from this requirement.

**Table 5:** Materials and components excluded from packaging elements

Packaging element	Excluded material or component <sup>5</sup>
Label or sleeve	<ul style="list-style-type: none"> <li>- PS label or sleeve in combination with a PET, PP, or HDPE packaging</li> <li>- PVC label or sleeve in combination with a PET, PP, or HDPE packaging</li> <li>- PETG label or sleeve in combination with PET packaging.</li> <li>- Sleeve labels made from a polymer different from the polymer from which the bottle is produced</li> <li>- Labels or sleeve (in-mold labeling) metalized or welded to a package body</li> </ul>
Closure	<ul style="list-style-type: none"> <li>- PS closure in combination with a PET, PP, or HDPE packaging</li> <li>- PVC closure in combination with a PET, PP, or HDPE packaging</li> <li>- PETG closures and/or closure material with a density of above 1 g/cm<sup>3</sup> in combination with a PET packaging</li> <li>- Closures made of metal, glass, EVA</li> <li>- Closures (or part of) made of silicone. Exempted are silicone closures with a density &lt; 1 g/cm<sup>3</sup> in combination with a PET packaging and silicone closures with a density &gt; 1 g/cm<sup>3</sup> in combination with PP or HDPE packaging</li> <li>- Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened</li> </ul>
Barrier coatings	<ul style="list-style-type: none"> <li>- Polyamide, EVOH, functional polyolefins, metalized and light blocking barriers</li> </ul>

**Assessment and verification:** The applicant shall submit a signed declaration of conformity stating the material composition of the package (including primary package sample, container, label/sleeve, adhesives, closure, and barrier coating).

In addition, it is obliged to comply with the requirements specified in Articles 9 and 15 regarding packaging production and placing on the market in the Regulation on the Control of Packaging

<sup>5</sup> EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, PET — Polyethylene terephthalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PVC — Polyvinylchloride

Wastes, dated 27.12.2017 and numbered 30283, published by the Ministry of Environment, Urbanization and Climate Change in the Official Gazette; Article 16 on heavy metal concentrations and articles 19, 20, 21 and 22 on recycling/recovery. The provisions regarding the explanations regarding the wastes, recycling processes, and disposal methods in the Annexes of the relevant Regulation shall also be taken into account.

In addition, recyclable packaging materials produced from recyclable raw materials shall be used if technically possible and feasible.

**Assessment and verification:** The applicant shall request the use of at least 80% recycled secondary raw material in the primary packaging material to be purchased from the packaging manufacturer from which the packaging is purchased. The applicant must procure secondary packaging from manufacturers using at least 40% recycled material. The applicant shall submit a self-signed declaration of conformity by attaching a signed declaration from the packaging manufacturer, stating that these ratios are used in the packages produced and containing the raw material input registration copies of the process, if possible, without disclosing trade secrets.

### **Criterion 7. Waste management**

The applicant shall prepare a Waste Management Plan, which includes the management of waste and residues that may occur in all steps from the raw material procurement to the placing on the market of the product. Waste Management shall start from the choices at the purchasing stage and include the planning of remedial practices for each year to avoid waste.

For each type of waste, information on the processes and activities where the waste is generated, the amount of waste collected annually, the distribution of the total waste amount according to recovery and disposal, the reasons for sending it to disposal shall be recorded, and the recovery targets for the coming years shall be specified. It will be essential that decomposable waste types such as cardboard, paper, and glass are collected separately and sent to licensed recycling facilities, only in cases where recycling is not possible.

**Assessment and verification:** The applicant shall have the "Zero Waste" basic document within its scope and shall have the Waste Management Plan covering the provisions of the relevant regulations, official registration/waste transportation, etc. information and documents shall be submitted for approval in the application file.

In accordance with the "Waste Management Regulation" dated 02.04.2015 and numbered 29314 published in the Official Gazette by Ministry of Environment, Urbanization and Climate Change, the prevention, reduction, reuse, recycling and recovery and final disposal of waste, and control and inspection after disposal shall be carried out. Accordingly, the Waste Management Plan shall include long-term policies that will ensure waste management in an environmentally compatible manner.

In accordance with the "Packaging Waste Control Regulation" dated 27.12.2017 and numbered 30283, to protect natural resources and ensure production in line with sustainable development goals, the formation of packaging wastes is prevented, and in cases where production is unavoidable, they are reused, recycled, recovered and used as an energy source is essential.



Separate collection of wastes shall be ensured as in the examples regarding the collection system specified in Annex 5 of the "Zero Waste Regulation" dated 12.07.2019 and numbered 30829. It shall be carried out together with the existing waste management systems in line with the implementation guide for the enterprises prepared by the Ministry for the monitoring and operation of the zero-waste management system.

The applicant shall submit a declaration stating that the product has been evaluated according to the requirements of the Waste Management Plan established under the relevant Legislation.

## **Criterion 8: Organic and Natural Content**

### **(a) Organic Content**

If there is an "organic" claim on the product, the organic content of the product must consist of at least 95% of components produced in accordance with the principles of organic farming activities or directly obtained from nature. This criterion is not required for products that do not have an "organic" claim.

**Assessment and verification:** The applicant, for the percentages of organic content, entered into force with the Authority's Approval dated 28.10.2020 and numbered E.2624, the provisions of which were carried by the Ministry of Health, Turkish Medicines and Medical Devices Agency, according to Article 7 of the "Information Guide for Cosmetic Product Manufacturers, Consumers, Service Provided Institutions and Professional Persons Applying Professional Products", in order to certify the products in terms of organic content, a document showing the content of the product or documentation showing the organic content within the scope of the internationally accepted TS ISO 16128-1/ISO 16128-1, ISO 16128-2 standards shall be submitted.

The applicant must submit a declaration stating that the organic content in the product has been calculated as desired and is at least 95%. In this regard, if it has a valid national/international certificate, this certificate is accepted.

The applicant shall submit a document proving that the organic content in the product consists of products for which organic farming certificate has been issued by an accredited organization listed under the heading "Control and Certification Organizations Entrepreneur Lists Web Addresses" on the website of the Ministry of Agriculture and Forestry (<https://www.tarimorman.gov.tr/Konular/Bitkisel-Uretim/Organik-Tarim>).

### **(b) Natural Content**

Natural ingredient refers to the ingredients in the product formulation derived from plants and/or animals. This criterion is not required for products that do not have a "natural" claim.

The percentage of natural ingredients of a cosmetic product will be calculated as follows:

$$\text{Natural ingredient \% of total} = \left[ \frac{\text{final product weight} - \text{Total weight of non-natural ingredients} - \text{total weight of petrochemical components}}{\text{weight of all components}} \right] \times 100$$

**Assessment and verification:** The applicant, for the percentages of natural content, entered into force with the Authority's Approval dated 28.10.2020 and numbered E.2624, the provisions of which were carried by the Ministry of Health, Turkish Medicines and Medical Devices Agency, according to Article 7 of the "Information Guide for Cosmetic Product Manufacturers, Consumers, Service Provided Institutions and Professional Persons Applying Professional Products", in order to certify the products in terms of natural content, a document showing the content of the product or documentation showing the organic content within the scope of the internationally accepted TS ISO 16128-1/ISO 16128-1, ISO 16128-2 standards shall be submitted.

In this regard, if it has a valid national/international certificate, this certificate is accepted.

While obtaining the natural content, in accordance with Article 56 of the Constitution and Article 9 of the Environmental Law and to which we are a party. In accordance with international conventions such as the CITES Convention, the Ramsar Convention, the Convention on Biological Diversity, the legislative requirements regarding flora, fauna, and wildlife and all protected species must be complied with.

The applicant shall submit a declaration stating that the natural content contained in the product has been calculated as desired.

#### **Criterion 9. Fitness for use**

A cosmetic product placed on the market, in accordance with Article 6 of the Cosmetics Regulation dated 23.05.2005 and numbered 25823 published in the Official Gazette, shall be safe for human health when applied under normal and foreseeable conditions or when applied according to the conditions of use recommended by considering the presentation, labeling, use of the product or the information provided by the manufacturer. While testing the suitability of the product for use, the "Guide on the Analysis of Cosmetic Products" and "Guide on Microbiological Controls of Cosmetic Products" prepared by the Ministry of Health Turkish Medicines and Medical Devices Agency based on the 6th, 11th, 16th, and 20th articles of the Cosmetics Regulation documents shall be considered.

**Assessment and verification:** The applicant shall comply with the obligations specified in Article 4 (c), (d), and (e) clauses of the Cosmetic Law dated 30.03.2005 and numbered 5324 published in the Official Gazette. In order to test the effectiveness of the product, the applicant must submit the results of the analyzes to be carried out in accordance with the TS EN ISO/IEC 17025, TS 5822-1 ISO 5725-1, TS 5822-2 ISO 5725-2, TS 5822-3 ISO 5725-3, TS 5822-4 ISO 5725-4, TS 5822-5, ISO 5725-5 ve TS 5822-6 ISO 5725-6 standards specified in Article 6 of the "Guideline for the Analysis of Cosmetic Products", adhering to the requirements of Article 7 of the Cosmetics Regulation. It is accepted if the company has current and up-to-date analyses in this field.

The applicant may support the claims of the product to be put on the market by implementing best practices, for the corroborative evidence referred to in Article 11 and 2<sup>nd</sup> paragraph of the "Guideline on Claims of Cosmetic Products", such as experimental studies like instrumental or biochemical methods, including (but not limited to) in silico, in vitro, ex vivo studies, on volunteers studies (efficacy study, safety study, etc.), investigator evaluations, sensory evaluations.

The applicant shall submit a declaration stating that the product is suitable for use under the relevant Legislation.

#### **Criterion 10. Information appearing on the Environmental Label**

The following information shall be placed on the product along with the environmental label:

The environmental label shall be placed on the product packaging in dimensions of 2\*2 cm. Under the label, the document number in 6-point font and "The use of the environmental label in this product has been approved by the Ministry of Environment, Urbanization and Climate Change in accordance with the Environmental Label Regulation published in the Official Gazette dated 19.10.2018 and numbered 30570 due to its environmental performance." should be included.

If the product is approved during the application process, it can be included in the following statements.

- Limited impact on the aquatic environment
- Sustainable use of raw materials,
- Restriction of harmful chemicals in the manufacturing process.

***Assessment and verification:*** The applicant shall provide a sample of the product label or the design of the packaging on which the Turkish Environmental Label is placed, together with a signed declaration of conformity. The Environmental Label shall be placed on the packaging of products of different sizes, in the dimensions determined by the Ministry of Environment, Urbanization and Climate Change. Approval of the Ministry is required for it to take place in different sizes.