# ENVIRONMENTAL LABEL CRITERIA FOR THE PERSONAL CARE PRODUCT GROUP

**Article 1**– These criteria have been established within the scope of the Environmental Label Regulation published in the Official Gazette dated 19.10.2018 and numbered 30570.

Article 2– The Personal Care and Cosmetic Product Groups, in accordance with the provisions of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184 (duplicate), comprise all substances or mixtures intended to be applied to the external parts of the human body—epidermis, nails, hair, scalp, lips, and external genital organs—or to the teeth and mucous membranes of the oral cavity, with the sole or primary purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition, or correcting body odors. These criteria cover the Personal Care Product Group<sup>1</sup>.

Article 3– These criteria do not cover products used for disinfectant or antibacterial purposes.

**Article 4**— Within the scope of the Environmental Label Regulation published in the Official Gazette dated 19.10.2018 and numbered 30570, products in the Personal Care Product Group must meet these criteria in order to be eligible for an environmental label.

**Article 5**– The assessment and verification requirements for the Environmental Label criteria defined for the Personal Care Product Group shall be valid for 5 (five) years. Within this period, the criteria may be updated by the Environmental Label Board as deemed necessary. The validity period of the criteria may be extended upon the approval of the Environmental Label Board.

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<sup>&</sup>lt;sup>1</sup> In accordance with the product categories listed in Annex IX of the Cosmetics Regulation published in the Official Gazette dated 08/05/2023 and numbered 32184 (Duplicate), the product types included in the Personal Care Product Group are provided in this document under Annex I.

#### ASSESSMENT AND VERIFICATION REQUIREMENTS

#### (a) Requirements

Specific assessment and verification requirements are provided for each criterion.

Where declarations, documentation, analyses, test reports, or other evidence are required to demonstrate compliance with the criteria, such information may be provided by the applicant, the supplier, or both.

The Ministry recognizes tests conducted by laboratories accredited by an accreditation body that is a party to the International Laboratory Accreditation Cooperation (ILAC) – Mutual Recognition Arrangement (MRA), in accordance with TS EN ISO/IEC 17025. Institutions accredited by TÜRKAK can be accessed via <a href="https://secure.turkak.org.tr/kapsam/search">https://secure.turkak.org.tr/kapsam/search</a>. For test methods that are mandatory within the scope of assessment and verification requirements, if it is documented that no accredited institution exists, the TS EN ISO/IEC 17025 accreditation requirement shall not be sought. If deemed appropriate, the Ministry may request supporting documentation and may conduct independent verification.

When generating data related to the classification of substances or mixtures, the provisions of the "Regulation on Test Methods to Be Applied in Determining the Physico-Chemical, Toxicological and Ecotoxicological Properties of Substances and Mixtures" published in the Official Gazette dated 11.12.2013 and numbered 28848 (Second Duplicate), or scientifically recognized international principles or methods verified in accordance with international procedures, should be taken into account.

The applicant must fulfill the obligations under Law No. 7223 on Product Safety and Technical Regulations and Law No. 2872 on Environment, along with the relevant secondary legislation enacted pursuant to these laws. Accordingly, the applicant is required to submit documents such as the Environmental Impact Assessment (EIA) Decision, Environmental Permit Certificate, Zero Waste Certificate, Waste Management Plan, and other documents as requested by the Ministry.

It is necessary to demonstrate the biodegradability and toxicity effects on aquatic organisms of personal care products. For this purpose, the "Detergent Ingredient Database" (DID List)<sup>2</sup> developed by the EU Commission is used. This list contains information on the biodegradability and aquatic toxicity of the most commonly used ingredients in detergent and cosmetic

https://circabc.europa.eu/ui/group/0e3024d9-38be-415b-b141-c05d5d31dd92/library/057790be-097a-4f45-b0e3-21b81580ec60/details https://circabc.europa.eu/ui/group/0e3024d9-38be-415b-b141-c05d5d31dd92/library/9560fcf6-07e3-44c8-b63c-614e0f0704b8/details

formulations. It will be used to derive data for calculations related to the Critical Dilution Volume (CDV) and to assess the biodegradability of substances used in the product. For substances not found in the DID List, guidance is provided on how to estimate or derive the relevant data. The most recent version of the DID List can be obtained from the EU Ecolabel website.

Additionally, the following information must be provided to the Ministry by the applicant:

- (i) The product formulation must be submitted in a clear and comprehensible manner for the verifier, including the trade name, chemical name, CAS number, and INCI (International Nomenclature Cosmetic Ingredient) definitions, DID number<sup>3</sup>, input quantity with and without water, and the function and chemical structure of all ingredients regardless of concentration. The maximum values declared by the company during the process will be used in calculations.
- (ii) In accordance with the "Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals (KKDIK)" published in the Official Gazette dated 23.06.2017 and numbered 30105 (duplicate), a Safety Data Sheet (SDS) must be provided for each input substance or mixture. If an SDS is not available for a substance that is a component of a mixture, the applicant must provide the SDS for the mixture. As stated in Article 6 of the "Guideline on the Analysis of Cosmetic Products" published by the Ministry of Health, Turkish Medicines and Medical Devices Agency, analytical methods used for checking compliance with Article 15 of the Cosmetic Products Regulation must be validated according to 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 (six-part standards for measurement methods and result accuracy), or applicable IUPAC guidelines.

According to Article 13 of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184 (duplicate), a "Cosmetic Product Safety Assessment Report" must be prepared by qualified personnel before a cosmetic product is placed on the market. The safety assessment, detailed in Annex I/B, must be conducted by an individual holding a diploma or other official qualification recognized by the Agency, evidencing the completion of a theoretical and practical university education in pharmacy, toxicology, medicine, or a similar discipline. Annex I/B also outlines the minimum required information regarding the physical, chemical, and microbiological properties of the products. The Cosmetic

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<sup>&</sup>lt;sup>3</sup> DID number refers to the entry number of the input substance in the DID (Detergent Ingredient Database) List.

Product Safety Assessment Report is expected to include such information as required for demonstrating compliance with the criteria.

If the product for which the Environmental Label application is submitted has already completed all processes and is currently on the market, the existing test or measurement results will be accepted, provided they are still valid. However, outdated measurement and/or test results must be repeated. After obtaining the Environmental Label, the test and measurement results submitted during the application process must be updated and submitted to the Ministry annually.

#### (b) Measurement Thresholds

For the Personal Care Product Group, compliance with the defined criteria is required for impurities present at or above 0.01% by weight in the final formulation of rinse-off products and 0.001% by weight in the final formulation of leave-on products, under clause (b) of the "Excluded and Restricted Chemicals Criterion" and clauses (c), (d), and (e) concerning fragrance substances, preservatives, and colorants, respectively (see Table 1).

Table 1: Applicable threshold levels for substances used in personal care products, specified per criterion.

Criteri	on	Fragrances	Preservatives	Colorants	Impurities	Other Substances (e.g. surfactants, UV filters)
Cuitanian 1	rinse-off	no limit <sup>4</sup>	no limit <sup>4</sup>	no limit 4	≥0,01	no limit <sup>4</sup>
<u>Criterion 1</u>	leave-on	no limit <sup>4</sup>	no limit 4	no limit 4	≥0,001	no limit <sup>4</sup>
Criterion 2	rinse-off	no limit 4	no limit 4	no limit 4	≥0,01	no limit <sup>4</sup>
CHIEHOH 2	leave-on	no limit 4	no limit 4	no limit <sup>4</sup>	≥0,001	no limit <sup>4</sup>
Criterion 3	rinse-off	no limit 4	no limit 4	no limit <sup>4</sup>	≥0,01	no limit <sup>4</sup>
Criterion 4(a)	rinse-off and leave-on	no limit				
Criterion 4(b)/(i)	rinse-off and leave-on	no limit <sup>4</sup>	no limit <sup>4</sup>	no limit <sup>4</sup>	no limit <sup>4</sup>	no limit
Criterion 4(b)/(ii)	rinse-off and leave-on	no limit				
Cuitanian A(la)/(iii)	rinse-off	≥0,01	$\geq 0.01^5$	$\geq 0.01^5$	≥0,01	≥0,01
Criterion 4(b)/(iii)	leave-on	≥0,001	$\geq 0.001^5$	$\geq 0.001^5$	≥0,001	≥0,001
Criterion 4(c)	rinse-off	no limit <sup>4</sup>	not applicable	not applicable	≥0,01	not applicable
CHICHOH 4(C)	leave-on	no limit 4	not applicable	not applicable	≥0,001	not applicable
Criterion 4(d)	rinse-off	not applicable	no limit <sup>4</sup>	not applicable	≥0,01	not applicable
<u>CHCHOH 4(u)</u>	leave-on	not applicable	no limit 4	not applicable	≥0,001	not applicable
Criterion 4(e)	rinse-off	not applicable	not applicable	no limit <sup>4</sup>	≥0,01	not applicable
	leave-on	not applicable	not applicable	no limit <sup>4</sup>	≥0,001	not applicable
Criterion 4(f)	leave-on	not applicable	not applicable	not applicable	≥0,001	no limit <sup>4,6</sup>

 $<sup>^4</sup>$  "No limit" means: Regardless of the concentration of all substances, except for impurities that may be present up to 0.01% by weight in the final formulation of rinse-off products and up to 0.001% by weight in the final formulation of leave-on products.

<sup>&</sup>lt;sup>5</sup> There is no concentration limit for preservative and colorant substances classified with hazard codes H317 and H334.

<sup>&</sup>lt;sup>6</sup> Applicable only to UV filters.

#### ENVIRONMENTAL LABEL CRITERIA

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

At least 20% of the palm oil, palm kernel oil, and their derivatives used in the product—whether as raw materials or ingredients—must be certified under one of the following schemes or an equivalent certification: RSPO<sup>7</sup>, ISCC<sup>8</sup>, Rainforest Alliance, ISPO<sup>9</sup>, MSPO<sup>10</sup>, or UEBT<sup>11</sup>. For the proportion that is not certified under RSPO or an equivalent scheme, compensation must be made using the RSPO PalmTrace credit system.

The RSPO or equivalent certificate obtained for palm oil, palm kernel oil, and their derivatives must be aligned with one of the following supply chain models:

- Identity Preserved (IP);
- Segregated (SG);
- Mass Balance (MB).

The applicant must have a sustainable procurement policy that supports and commits to the purchase of certified raw materials used for palm oil, palm kernel oil, and their derivatives, either as base materials or ingredients. In cases where certified materials are not available, the policy must include the use of RSPO PalmTrace credits to offset uncertified amounts, and must commit to increasing the share of certified materials by 20% every five years after the environmental label is granted.

#### **Assessment and Verification:**

The applicant must submit certification documents showing that at least 20% of the palm oil, palm kernel oil, and their derivatives used in the product comply with one of the IP, SG, or MB supply chain models under RSPO, ISCC, Rainforest Alliance, ISPO, MSPO, or UEBT schemes.

If the applicant holds a different certificate aligned with IP, SG, or MB models, they must also submit a comparative evaluation report showing that its criteria are equivalent to those of RSPO, ISCC, Rainforest Alliance, ISPO, MSPO, or UEBT.

The applicant must provide evidence of RSPO PalmTrace credits purchased to compensate for the uncertified portion.

<sup>&</sup>lt;sup>7</sup> Roundtable on Sustainable Palm Oil

<sup>&</sup>lt;sup>8</sup> International Sustainability Standard

<sup>&</sup>lt;sup>9</sup> Indonesian Sustainable Palm Oil

<sup>&</sup>lt;sup>10</sup> Malaysian Sustainable Palm Oil

<sup>&</sup>lt;sup>11</sup> Union for Ethical Bio Trade

The applicant must submit a signed declaration confirming that at least 20% of the palm oil, palm kernel oil, and their derivatives used in or for the product are certified under one of the aforementioned schemes, or under an equivalent scheme that has been comparatively assessed; and that RSPO PalmTrace credits have been purchased for any uncertified proportion.

Finally, the applicant must provide a copy of the sustainable procurement policy that supports and commits to: the purchase of certified palm-based raw materials; use of RSPO PalmTrace credits in the absence of certified materials; and increasing the proportion of certified content by 20% every five years following the award of the environmental label.

# Criterion 2. Biodegradability

# (a) Biodegradability of Rinse-off Products

#### 1. Biodegradability of Surfactants

All surfactants present in the product must be readily or inherently biodegradable under aerobic conditions and biodegradable under anaerobic conditions.

Surfactants used in toothpastes for cleaning and/or foaming purposes are exempt from the requirement of being biodegradable under anaerobic conditions.

# 2. Biodegradability of Organic Substances

The total concentration of organic substances in the product that are not biodegradable under aerobic conditions (either readily or inherently) (aNBO) and those not biodegradable under anaerobic conditions (anNBO) must not exceed the limit values specified in Table 2.

aNBO (product) = Σ aNBO<sub>(i)</sub> (amount of organic compound in the reference dose, gr)
(i) organic substance, if readily biodegradable (R), aNBO<sub>(i)</sub> = 0
(i) organic substance, if inherently biodegradable (I), aNBO<sub>(i)</sub> = 0

anNBO =  $\Sigma$  anNBO<sub>(i)</sub> (amount of organic compound in the reference dose, gr)

(i) organic substance, if biodegradable under anaerobic conditions (Y), anNBO<sub>(i)</sub> = 0

Table 2: Concentration limit values for organic substances in the product that are not biodegradable under aerobic and anaerobic conditions, specified by product type.

Product Type	aNBO (mg/g AC <sup>12</sup> )	anNBO (mg/g AC)
<b>In Solid Form:</b> Shampoo, Soap, Shower Preparations (Bath Salt etc.), Toothpaste	5	5
In Solid Form: Shaving Soap	10	10
External Genital Area Care Products (Gel, Cleanser etc.)	15	15

<sup>&</sup>lt;sup>12</sup> Active Content

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Product Type	aNBO (mg/g AC <sup>12</sup> )	anNBO (mg/g AC)
Hair Conditioner	15	15
<b>In Liquid Form:</b> Soap, Shower Preparations (Shower Gel etc.)	15	15
<b>Rinse-off:</b> Skin Care Products (Exfoliants, Facial Cleansing Gel/Foam etc.)	15	15
In Liquid Form: Shampoo	20	20
Toothpaste and Mouthwash (and Mouth Sprays)	15	15
Shaving Foam, Shaving Gel, Shaving Cream	70	40
Other Rinse-off Products 13	15	15

#### **Assessment and Verification:**

The applicant must submit documentation regarding the biodegradability of surfactants and organic substances in the product, along with calculations related to aNBO (aerobically non-biodegradable organic substances) and anNBO (anaerobically non-biodegradable organic substances). In calculating aNBO and anNBO values, the 2023 file of the Detergent Ingredient Database (DID List) should be used as a reference for the corresponding values of organic substances.

Data on the aerobic and anaerobic biodegradability of raw materials are provided in Section A of the DID List. If the relevant information is not available in Section A, calculations for aNBO and anNBO must be made based on the methods specified in Section B of the DID List, including tests for ready aerobic biodegradability (OECD 301 A [TS EN ISO 7827], OECD 301 B [TS EN ISO 9439], OECD 301 C, OECD 301 D [TS EN ISO 10707], OECD 301 E, OECD 301 F [TS EN ISO 9408], OECD 310 [TS EN ISO 14593]), inherent aerobic biodegradability (OECD 302 A-C), and anaerobic biodegradability (OECD 311, TS EN ISO 11734, or ECETOC No. 28). The results of these tests must be documented and submitted.

If the calculation of aNBO and anNBO values cannot be performed in accordance with the requirements above, substances other than surfactants may be exempt from the anaerobic biodegradability criterion if they meet one of the following three conditions:

- readily biodegradable and low adsorption (A < 25%);
- readily biodegradable and high desorption (D > 75%);
- readily biodegradable and not bioaccumulative (BCF  $\leq$  500 or log Kow  $\leq$  4.0).

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<sup>&</sup>lt;sup>13</sup> Refers to other rinse-off personal care products not listed in Table 1.

As stated in Article 5, Paragraph 3 of the Regulation on the Test Methods to Be Applied in Determining 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 numbered 28848 (Second Duplicate), test methods such as C.4-A through C.4-F listed in Annex I/C of the Regulation may also be used for determining the ecotoxicological properties derived from the intrinsic characteristics of substances and mixtures. For adsorption and desorption tests, the methods described under Section C.18: Adsorption/Desorption Using a Batch Equilibrium Method in Annex I/C of the same Regulation should be followed.

The applicant must submit a declaration stating that the product does not exceed the aNBO and anNBO threshold values given in Table 2.

# (b) Aquatic Toxicity and Biodegradability of Leave-on Products

At least 95% (by weight) of the total amount of organic substances present in the product must meet at least one of the following requirements:

- Readily biodegradable (OECD 301 A–F)
- Lowest aquatic toxicity: NOEC/ECx > 0.1 mg/L or EC/LC50 > 10.0 mg/L, and not bioaccumulative
- Lowest aquatic toxicity: NOEC/ECx > 0.1 mg/L or EC/LC50 > 10.0 mg/L, and potentially biodegradable (OECD 302 A–C)
- Lowest aquatic toxicity: NOEC/ECx > 0.1 mg/L or EC/LC50 > 10.0 mg/L, and not bioavailable (molecular weight > 700 g/mol)

UV filters with sun protection functions used in leave-on products are exempt from this criterion.

#### **Assessment and Verification:**

The applicant must refer to the 2023 version of the Detergent Ingredient Database (DID List) regarding the biodegradability of organic substances.

Data on the ready biodegradability of raw materials are included in Section A of the DID List. If the relevant information is not available in Section A, calculations must be based on the procedures described in Section B, including ready aerobic biodegradability tests (OECD 301 A [TS EN ISO 7827], OECD 301 B [TS EN ISO 9439], OECD 301 C, OECD 301 D [TS EN ISO 10707], OECD 301 E, OECD 301 F [TS EN ISO 9408], OECD 310 [TS EN ISO 14593])

and inherent aerobic biodegradability tests (OECD 302 A–C). Documentation of the results must be provided.

As specified in Article 5, Paragraph 3 of the Regulation on the Test Methods to Be Applied in Determining 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 numbered 28848 (Second Duplicate), appropriate test methods listed in Annex I/C (e.g., C.4-A through C.4-F) may be used to determine ecotoxicological properties stemming from the intrinsic characteristics of substances and mixtures.

For chronic aquatic toxicity (NOEC) and acute aquatic toxicity (LC50/EC50), data from Section A of the DID List should be used. If data are not available, calculations must be carried out using the OECD 202 and OECD 201 tests for acute aquatic toxicity, and OECD 202 Part 2 or OECD 211 for chronic aquatic toxicity. Documentation of the results must be submitted.

For bioaccumulation potential, calculations must be performed in accordance with OECD 107 or OECD 117, and results must be documented.

For molecular weight, supporting documents must be provided showing the molecular formula and molecular weight calculation.

#### **Criterion 3. Aquatic Toxicity: Critical Dilution Volume (CDV)**

The Critical Dilution Volume (CDV) estimates the impact of a product on freshwater ecosystems by calculating the volume of natural water required to dilute a given amount of the product (or functional unit) to a concentration at which no foreseeable harmful effects on the aquatic environment are expected. CDV is calculated using the following equation:

 $CDV_{chronic}$  (product) =  $\sum CDV_{chronic}$  [(i) substances] =  $\sum$  (weight<sub>(i)</sub> x DF<sub>(i)</sub>) x (1000/TF<sub>chronic</sub>(i)) weight<sub>(i)</sub>: the weight corresponding to 1 gram of AC in substance (i) (g);

DF<sub>(i)</sub>: the degradation factor of substance (i);

TF<sub>chronic</sub>(i): the chronic toxicity factor of substance (i) (mg/L).

Total CDV<sub>chronic</sub> value of the product, must not exceed the limit values specified in Table 3:

Table 3: CDV<sub>chronic</sub> limit values by product type.

Product Type	CDV <sub>chronic</sub> (L/g AC)
<b>In Solid Form:</b> Shampoo, Soap, Shower Preparations (Bath Salt etc.), Shaving Soap, Toothpaste	2,200

Product Type	CDV <sub>chronic</sub> (L/g AC)
<b>In Liquid Form:</b> Soap, Shower Preparations (Shower Gel, Shower Foams etc.)	10,000
In Liquid Form: Shampoo	11,000
External Genital Area Care Products (Gel, Cleanser etc.)	12,000
Hair Conditioner	12,000
<b>Rinse-off:</b> Skin Care Products (Exfoliants, Facial Cleansing Gel/Foam etc.)	12,000
Shaving Foam, Shaving Gel, Shaving Cream	12,000
Toothpaste and Mouthwash (and Mouth Sprays)	12,000
Other Rinse-off Products 14	12,000

#### **Assessment and Verification:**

The applicant must calculate the product's  $CDV_{chronic}$  value. The DF (Degradation Factor) and  $TF_{chronic}$  (Chronic Toxicity Factor) values must be obtained from Section A of the DID List. If the DF and  $TF_{chronic}$  values for a given input substance are not available in Section A, the applicant must calculate the required values in accordance with the procedures specified in Section B of the DID List and provide supporting documentation.

Additionally, the provisions outlined in Article 5, Paragraph 3 of the "Regulation on the Test Methods to Be Applied in Determining 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 numbered 28848 (Second Duplicate), must be taken into account.

The applicant must also submit a declaration stating that the product does not exceed the CDV limit values specified in Table 3.

#### **Criterion 4. Excluded and Restricted Chemicals**

#### (a) Excluded Chemicals

The following substances and mixtures must not be present either in the product formulation or in the content of any mixture added to the formulation:

- Linear alkylbenzene sulfonate (LAS), alkylphenol ethoxylates (APEOs), and other alkylphenol derivatives
- Nitrilotriacetic acid (NTA)
- Diethylenetriamine pentaacetic acid (DTPA) and its salts

<sup>&</sup>lt;sup>14</sup> Refers to other rinse-off personal care products not listed in Table 2.

- Nitro musks and polycyclic musks
- Octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), and dodecamethylcyclohexasiloxane (D6) 15
- Butylated hydroxytoluene (BHT<sup>16</sup>) and butylated hydroxyanisole (BHA)
- Ethylenediaminetetraacetic acid (EDTA) and its salts <sup>17</sup>
- Triclosan, formaldehyde, and formaldehyde-releasing agents
- Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), atranol, and chloroatranol
- Microplastics and nanosilver
- Phthalates
- Phosphates
- Phosphonates<sup>18</sup>
- Fragrances (benzyl salicylate, butylphenyl methylpropional, tetramethyl acetyloctahydronaphthalenes [OTNE])
- Sodium hypochlorite, chloramine, and sodium chlorite
- Isoflavones: daidzein, genistein
- Preservatives (benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan)
- UV filters (benzophenone-1, benzophenone-2, ethylhexyl methoxycinnamate)
- Boric acid, borates, or perborates
- Perfluorinated and polyfluorinated substances (PFASs)
- Sodium lauryl sulfate (SLS) <sup>19</sup>

#### **Assessment and Verification:**

The applicant must submit the product formulation along with a declaration of conformity confirming that the listed substances and/or mixtures have not been included in the product. This declaration must be supported by statements from the mixture manufacturers and must also take into account Annex II of the Cosmetic Products Regulation published by the Ministry of Health on 08.05.2023 in Official Gazette No. 32184.

<sup>&</sup>lt;sup>15</sup> When each substance is present at concentrations equal to or greater than 0.1% by weight.

<sup>&</sup>lt;sup>16</sup> BHT may only be used in perfumes; the total BHT content must be below 100 ppm in the perfume and below 0.0010% by weight in the final product.

<sup>&</sup>lt;sup>17</sup> Excluding bar soap, liquid soap, shampoo, and shower gel. When used in bar soap, the amount must not exceed 0.06% by weight; in liquid soap, shampoo, and shower gel, the amount must not exceed 0.05% by weight.

<sup>&</sup>lt;sup>18</sup> Excluding bar soap. When used in bar soap, the amount must not exceed 0.06% by weight.

<sup>&</sup>lt;sup>19</sup> Only in toothpaste.

# (b) Hazardous Chemicals

Within the scope of Annex I of the Regulation on the Classification, Labelling, and Packaging of Substances and Mixtures, published in the Official Gazette dated 11.12.2013 and numbered 28848 (Second Duplicate):

(i) Substances classified as hazardous to the environment (with hazard codes H410, H411, H412) must not exceed the maximum allowable concentration in the product as calculated by the following method:

$$100 \times c[H410] + 10 \times c[H411] + c[H412] \le \%2.5$$

c: the portion of the classified substance measured as a percentage by weight of the product. In zinc-based ointments/creams, zinc compounds (classified as H410) may be present up to a maximum of 25% and, in such cases, are exempt from the above calculation.

(ii) According to the list in Table 4, substances corresponding to hazard statements classified as "carcinogenic, mutagenic, or toxic to reproduction" may not be present in the final product or its components at any concentration.

Table 4: Excluded hazard classes, categories, and associated hazard statements.

Carcinogenic, Mutagenic, or Reproductive Toxicants		
Category 1A ve 1B	Category 2	
H340: May cause genetic defects.	H341: Suspected of causing genetic defects	
H350: May cause cancer.	H351: Suspected of causing cancer.	
H350i: May cause cancer by inhalation.		
H360F: May damage fertility.	H361f: Suspected of damaging fertility.	
H360D: May damage the unborn child.	H361d: Suspected of damaging the unborn	
11300D. Way damage the unborn child.	child.	
H360FD: May damage fertility. May damage	H361fd: Suspected of damaging fertility.	
the unborn child.	Suspected of damaging the unborn child.	
H360Fd: May damage fertility. Suspected of	H362: May cause harm to breast-fed	
damaging the unborn child.	children.	
H360Df: May damage the unborn child.		
Suspected of damaging fertility.		

(iii) According to the list in Table 5, substances corresponding to hazard statements classified under "acute toxicity, specific target organ toxicity, respiratory and skin corrosion, hazardous to the aquatic environment, corrosive substances, and harmful to the ozone layer" must not be used at concentrations equal to or greater than 0.0100% by weight in rinse-off products and 0.0010% by weight in leave-on products.

Substances or mixtures that have been processed to alter their properties and are thus no longer bioavailable, or have undergone chemical modification to eliminate the previously identified hazard, are exempt from <u>Criterion 4(b)</u>.

Table 5: Restricted hazard classes and categorization.

Acute Toxicity		
Category 1 ve 2	Category 3	
H300: Fatal if swallowed.	H301: Toxic if swallowed.	
H310: Fatal in contact with skin.	H311: Toxic in contact with skin.	
H330: Fatal if inhaled.	H331: Toxic if inhaled.	
H304: May be fatal if swallowed and enters airways.	EUH070: Toxic by eye contact.	
EUH059: Hazardous to the ozone layer.	EUH029: Contact with water liberates toxic gas.	
EUH031: Contact with acids liberates toxic	EUH032: Contact with acids liberates very	
gas.	toxic gas.	
Specific Target	Organ Toxicity	
Category 1	Category 2	
H370: Causes damage to organs.	H371: May cause damage to organs.	
H372: Causes damage to organs through	H373: May cause damage to organs through	
prolonged or repeated exposure.	prolonged or repeated exposure.	
Respiratory and	Skin Sensitization	
Category 1A	Category 1B	
H317: May cause an allergic skin reaction.	H317: May cause an allergic skin reaction.	
H334: May cause allergy or asthma	H334: May cause allergy or asthma	
	symptoms or breathing difficulties if inhaled.	
	Substances	
Category 1A, 1B ve 1C	Category 1	
H314: Causes severe skin burns and eye damage.	H318: Causes serious eye damage.	
Hazardous to the A	quatic Environment	
Category 1 ve 2	Category 3 ve 4	
H400: Very toxic to aquatic life.	H412: Harmful to aquatic life with long lasting effects.	
H410: Very toxic to aquatic life with long	H413: May cause long lasting harmful effects	
lasting effects.	to aquatic life.	
H411: Toxic to aquatic life with long lasting		
effects.		
Hazardous to the Ozone Layer		
H420: Harms public health and the		
environment by destroying ozone in the		
upper atmosphere.		

Table 6 lists substances and their associated hazard statements that are subject to exemption from criterion (iii) under certain conditions or directly.

Table 6: Hazard statements and exemption conditions related to the substances subject to exemption.

Substances	Hazard Statements	<b>Exemption Conditions</b>
Surfactants	H412: Harmful to aquatic life with long lasting effects.  H413: May cause long lasting harmful effects to aquatic life.	The total concentration in the final product must be less than 20% by weight.
Fragrances	H412: Harmful to aquatic life with long lasting effects. H413: May cause long lasting harmful effects to 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 harmful effects to aquatic life.	
Sodium Fluoride	H301: Toxic if swallowed.	In oral care and hygiene products, the total concentration must not exceed 0.15% by weight when calculated as fluoride (F) or when used as part of a mixture.

Criterion 4(b)(i) applies in addition to Criterion 4(b)(iii). This means that substances classified as H410, H411, and H412 may only be present in the formulation at concentrations of less than 0.0100% by weight for rinse-off products and less than 0.0010% by weight for leave-on products.

#### **Assessment and Verification:**

The applicant must submit a Safety Data Sheet (SDS) for each substance used in the product, along with a signed declaration from the mixture suppliers confirming that substances associated with the listed hazard statements are either not present in the product or, if present, do not exceed the specified threshold values.

For substances found in the final product after the production stage, with respect to the effects of "acute toxicity; specific target organ toxicity; respiratory or skin corrosion; hazardous to the aquatic environment; carcinogenic, mutagenic or toxic to reproduction; corrosive substances; hazardous to the ozone layer," the relevant test methods specified in the annex of the "Regulation on the Test Methods to Be Applied in Determining 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 numbered 28848 (Second Duplicate), Article 5, Paragraph 2, must be taken into account. In accordance with these test methods, the methods provided in OECD Guidelines for the Testing of Chemicals – Section 4: Health Effects (<a href="https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects">https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects</a> 20745788?page=1 ) may also be considered.

The applicant must also submit a declaration of compliance with <u>Criterion 4(b)</u> and the product formulation for each substance and mixture that is exempt and present at concentrations higher than 0.01%.

# (c) Fragrances

- (i) Any substance or mixture added to the product as a fragrance must be produced and used in accordance with the guidelines of the International Fragrance Association (IFRA), and the IFRA list<sup>20</sup> of fragrance components that are subject to exclusion, restriction, or special conditions must be taken into consideration.
- (ii) Each fragrance or flavoring substance classified as H317 ("may cause an allergic skin reaction") must not exceed 0.01% by weight in rinse-off products and 0.001% by weight in leave-on products.
- (iii) Fragrances used in products designed and marketed for children (ages 0–3) must not exceed the concentration limits set out in Annex III of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184.

#### **Assessment and Verification:**

The applicant must submit the

The applicant must submit the product formulation along with a signed declaration confirming that, apart from the substances and mixtures listed under <u>Criterion 4(a)</u>, no fragrance substances listed in Annex III of the Cosmetic Products Regulation (08.05.2023, Official Gazette No. 32184) are used in amounts exceeding the specified limits. This declaration must be supported by a statement from the fragrance manufacturer.

Additionally, in line with Article 5, Paragraph 2 of the Regulation on the Test Methods to Be Applied in Determining the Physico-Chemical, Toxicological, and Ecotoxicological Properties of Substances and Mixtures, published in the Official Gazette dated 11.12.2013 and numbered 28848 (Second Duplicate), "the toxicological properties stemming from the intrinsic

 $<sup>\</sup>frac{20}{\text{https://ifrafragrance.org/docs/default-source/51st-amendment/ifra-51st-amendment---index-of-ifra-standards.pdf?sfvrsn=6511ee03\_2}$ 

characteristics of substances and mixtures must be determined using the test methods listed in Section B of Annex I of that Regulation".

Moreover, the document titled "Analytical Methods for the Quantification of 57 Potential Inject-Ready Allergens (and Isomers) Present in Fragrance Ingredients by Gas Chromatography-Mass Spectrometry" <sup>21</sup>, published by the International Fragrance Association (IFRA), must also be taken into account. This method enables the identification and quantification of volatile compounds in a laboratory setting using GC-MS on "inject-ready" matrix samples and is compatible with gas chromatography.

#### (d) Preservatives

- (i) Preservatives present in the product must comply with the requirements specified in Criterion 4(b), and must not release or degrade into substances classified as hazardous.
- (ii) The product may contain preservatives that are not bioaccumulative (BCF < 500 or log  $K_{ow}$  < 4.0)  $^{22}$ .
- (iii) Preservatives classified as H317 or H334 must not be used in the product, regardless of their concentration.

#### **Assessment and Verification:**

The bioconcentration factor (BCF) is a value used to assess the environmental performance of a chemical in terms of its bioaccumulation potential. It is calculated as follows:

$$BCF = \frac{\text{concentration in the organism (typically fish)}\left(\frac{mg}{kg}\right)}{\text{concentration in the environment }\left(\frac{mg}{L}\right)}$$

As the BCF (bioconcentration factor) value of a chemical increases, its solubility in water decreases. The concentrations of the chemical in the organism and in the surrounding environment must be calculated in accordance with the test methods specified in OECD 305.

The octanol-water partition coefficient (log  $K_{ow}$ ) essentially measures the hydrophobic nature of a chemical. It is considered a useful indicator for evaluating the environmental fate of a chemical after its release. It is calculated as follows:

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https://ifrafragrance.org/docs/default-source/guidelines/23754\_gd\_2017\_04\_11\_ifra\_analytical\_method\_to\_quantify\_57\_suspected\_allergens\_(and\_is\_omers) in ready to inject fragrance materials by gc-ms-(3).pdf?sfvrsn=ad55ac1\_6

<sup>&</sup>lt;sup>22</sup> If both values are available, the higher one should be taken into account.

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

The log  $K_{ow}$  value of a chemical is inversely proportional to its solubility in water and directly proportional to its molecular weight. The concentrations of the chemical in octanol and in water must be calculated in accordance with the test methods specified in OECD 117.

The applicant must submit a declaration stating that the preservatives used in the product formulation do not exceed the BCF and log K<sub>ow</sub> threshold values.

The applicant must also submit a declaration confirming that the preservatives used in the product, excluding the substances and mixtures listed in <u>Criterion 4(a)</u>, comply with the threshold values specified in <u>Criterion 4(b)</u> and in Annex V of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184.

# (e) Colorants

- (i) Colorants classified as H317 or H334 must not be used in the product, regardless of their concentration.
- (ii) The product may contain colorants that are not bioaccumulative (BCF  $\leq$  500 or log K<sub>ow</sub>  $\leq$  4.0) <sup>23</sup>.
- (iii) Colorants approved for use in food are exempt from this criterion.

#### **Assessment and Verification:**

The bioconcentration factor (BCF) is a value used to assess the environmental performance of a chemical in terms of its bioaccumulation potential. It is calculated as follows:

$$BCF = \frac{concentration in the organism (typically fish) \left(\frac{mg}{kg}\right)}{concentration in the environment \left(\frac{mg}{L}\right)}$$

As the BCF (bioconcentration factor) value of a chemical increases, its solubility in water decreases. The concentrations of the chemical in the organism and in the surrounding environment must be calculated in accordance with the test methods specified in OECD 305.

The octanol-water partition coefficient (log  $K_{ow}$ ) essentially measures the hydrophobic nature of a chemical. It is considered a useful indicator for evaluating the environmental fate of a chemical after its release. It is calculated as follows:

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<sup>&</sup>lt;sup>23</sup> If both values are available, the higher one should be taken into account.

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

The log  $K_{ow}$  value of a chemical is inversely proportional to its solubility in water and directly proportional to its molecular weight. The concentrations of the chemical in octanol and in water must be calculated in accordance with the test methods specified in OECD 117.

The applicant must submit a declaration stating that the colorants used in the product formulation do not exceed the BCF and log K<sub>ow</sub> threshold values.

The applicant must also submit the product formulation along with a signed declaration confirming that the colorants used—excluding those listed under <u>Criterion 4(a)</u>—are included in the list set out in Annex IV of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184, and that they have been used in compliance with the specified limits.

#### (f) UV Filters

UV filters may only be used in products intended for sun protection (e.g., sunscreens) and multifunctional products with sun protection purposes, and solely for the purpose of protecting the user (not the product). All UV filters used in the product must either be non-bioaccumulative (BCF < 500 or log  $K_{\rm ow}$  < 4.0) or have the lowest measured toxicity value of NOEC/ECx > 0.1 mg/L or EC/LC50 > 10.0 mg/L<sup>24</sup>.

#### **Assessment and Verification:**

The applicant must submit a declaration of compliance with all the requirements mentioned above, supported by statements from suppliers. The applicant must also provide a signed declaration confirming that the UV filters used—excluding substances and mixtures listed under <u>Criterion 4(a)</u>—are included in the list specified in Annex VI of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184, and that they have been used in accordance with the specified limits.

# **Criterion 5. Energy Management**

Companies must hold the TS EN ISO 50001 Energy Management System certification, which serves as a guiding framework for the use of renewable energy sources, implementing energy-saving measures, and ensuring the efficient use of energy. Companies that do not hold this

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 $<sup>^{24}</sup>$  The higher of the measured BCF and log  $K_{ow}$  values, and the lower of the measured NOEC/ECx and EC/LC50 values should be taken into account.

certification must prepare an Energy Management Plan to achieve the objectives outlined within the scope of energy management.

#### **Assessment and Verification:**

The applicant must either obtain TS EN ISO 50001 Energy Management System certification or develop an Energy Management Plan within a system prepared by energy experts. The performance improvements achieved through the plan must be demonstrated using the "TS ISO 50015:2014 — Measurement and Verification of Energy Performance of Organizations" standard, and measurable progress must be proven. Enterprises that already hold the TS EN ISO 50001 certificate are considered to have met this criterion.

It is not mandatory for every enterprise to establish a full Energy Management System. Applicants without TS EN ISO 50001 certification must appoint an Energy Manager and conduct an energy efficiency assessment study. They must also implement practices to improve energy efficiency in accordance with Article 7 of the Energy Efficiency Law No. 5627, published in the Official Gazette dated 02.05.2007 and numbered 26510. Additionally, the provisions of the "Regulation on Increasing Efficiency in the Use of Energy Resources and Energy," published by the Ministry of Energy and Natural Resources in the Official Gazette dated 27.10.2011 and numbered 28097, should be utilized. Furthermore, it is mandatory to obtain an Energy Performance Certificate in accordance with the "Regulation on Energy Performance in Buildings," published in the Official Gazette dated 05.12.2008 and numbered 27075.

#### Criterion 6. Packaging

#### (a) Prerequisite

The applicant must meet at least one of the following prerequisites:

- Paper and cardboard packaging must be certified by the Forest Stewardship Council (FSC) or an equivalent certification scheme.
- Palm oil, palm kernel oil, and their derivatives must not be used as renewable raw materials in packaging materials.
- Primary packaging must contain at least 50% recycled material, and secondary packaging must contain at least 40% recycled material.

Bulk items/accessories sold with the product—such as brushes, applicators, or technical components—are exempt from the prerequisites and packaging calculations.

If none of the prerequisites are met, the requirements specified under the <u>Packaging Impact</u> Rate criterion must be fulfilled.

#### **Assessment and Verification:**

For the assessment and verification of the prerequisites listed above:

- The applicant must submit a declaration stating that the paper and cardboard packaging is FSC certified. The FSC certificate<sup>25</sup> belonging to the packaging manufacturer must be included in the application file.
- The applicant must submit a declaration from the packaging manufacturer stating that
  palm oil, palm kernel oil, and their derivatives are not used as renewable raw materials
  in the packaging materials. This declaration must also be included in the application
  file.
- If the packaging used is made from recycled material, the applicant must submit a signed declaration from the packaging manufacturer, accompanied—where possible and without disclosing trade secrets—by copies of input records for raw materials used in the process. This must be included in the application file.

# (b) Primary Packaging

Primary packaging refers to the packaging that is in direct contact with the product. Additional packaging, such as cardboard boxes, is not permitted for products offered for sale. Cardboard boxes used for transporting products to retail stores are not considered secondary packaging.

For products where the primary packaging is in tube form, secondary packaging is not permitted.

#### **Assessment and Verification:**

The applicant must submit a signed declaration stating that, unless technically required, only primary packaging will be used and that efforts will be made to reduce the amount of packaging.

For products using tubes as primary packaging, the applicant must submit a declaration confirming that no secondary packaging is used. If secondary packaging is used for tube-based or any other product, the applicant must submit a written justification to the Ministry explaining the necessity of such usage.

<sup>&</sup>lt;sup>25</sup> The "FSC Certificate Public Dashboard" can be used to access the certification database of FSC-certified packaging manufacturers.

# (c) Packaging Impact Ratio (PIR)

The Packaging Impact Ratio (PIR) is calculated for the primary packaging. If the product is sold in multiple packaging formats, the PIR must be calculated for each one. For each packaging format, the PIR must be less than 0.28 g of packaging per gram of product. Products packaged in metal aerosol containers are exempt from this requirement.

PIR must be calculated separately for each packaging format using the following formula:

$$PIR = \frac{(W + (W_{refill} x F) + N + (N_{refill} x F))}{(D + (D_{refill} x F))}$$

W: packaging weight (primary packaging + proportional weight<sup>26</sup> of secondary packaging, including labels)

W<sub>refill</sub>: weight of refillable packaging (primary packaging + proportional weight of secondary packaging, including labels) (g)

N: weight of non-renewable and non-recycled packaging (primary packaging + proportional weight of secondary packaging, including labels) (g)

N<sub>refill</sub>: weight of non-renewable and non-recyclable refillable packaging (primary packaging + proportional weight of secondary packaging, including labels) (g)

D: weight of the product contained in the primary packaging (g)

D<sub>refill</sub>: weight of the refilled product (g)

F: number of refills required to meet the total refillable quantity:

$$\mathbf{F} = \frac{\mathbf{V} \times \mathbf{R}}{\mathbf{V_{refill}}}$$

V: volume of the primary packaging (mL)

V<sub>refill</sub>: volume of the packaging used for refilling (mL)

R: refillable quantity; this represents the number of times the primary packaging can be refilled. If the F value is not a whole number, it must be rounded up to the next whole number.

If no refilling is carried out, the PIR must be calculated as shown below:

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<sup>&</sup>lt;sup>26</sup> The proportion of secondary packaging includes the proportional weight of the grouping packaging. For example, if two products are sold together in a grouped package, 50% of the total weight of the grouping packaging is considered; if three products are sold together, 33% of the total grouping packaging weight is taken into account, and so on.

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

The manufacturer must specify the intended number of refills, or use the default values of R = 5 for plastics and R = 2 for cardboard.

#### **Assessment and Verification:**

The applicant must submit the PIR calculation for the product. If the product is sold in different packaging formats (e.g., different volumes), a separate calculation must be provided for each package size to be covered by the Ecolabel.

The applicant must submit a signed declaration from the packaging manufacturer regarding the content of post-consumer recycled material or renewable-based material in the packaging, and, if applicable, provide a description of the refill system (types of refills, volumes). For the approval of refill packaging, the applicant or retailer must demonstrate that refills will be available for purchase on the market.

The applicant must provide third-party verification and traceability for the post-consumer recycled content. Although not mandatory, certificates from recyclers under a certification scheme following the TS EN 15343 standard may be used to support verification. Similarly, although not mandatory, product manufacturing certificates for converters under a certification scheme following a controlled blending model as described in ISO 22095 may be used to support verification.

#### (d) Design of Primary Packaging

**Rinse-off Products:** Refillable packaging and primary packaging for rinse-off products that can be manually opened and allow the remaining product to be extracted by adding water are exempt from this requirement and the associated calculation.

The primary packaging must be designed to facilitate accurate and easy dosing (e.g., by ensuring the top opening is not too wide) and to allow at least 95% of the product to be easily emptied from the container. The amount of product remaining in the container after consumer use (R) must be less than 5% and must be calculated as follows:

$$R = \frac{(m2 - m3)}{(m1 - m3)} \times 100 \, (\%)$$

m1: primary packaging and product (g)

**m2:** primary packaging and product remaining in the container after normal consumer use (g)

m3: emptied and cleaned primary packaging (g)

**Leave-on Products:** For packaging used for leave-on hair conditioners and creams, the packaging must either achieve a 90% emptying level or be equipped with a cap that can be removed without the use of tools.

The amount of product remaining in the container after consumer use (R) must be less than 10% and should be calculated using the same formula provided for rinse-off products.

#### **Assessment and Verification:**

If a refill system is applied, the applicant must submit a declaration explaining the system in use. If no refill system is applied, the applicant must calculate the amount of product remaining in the container (R) after consumer use. Additionally, a result report including the calculations of the remaining product must be submitted.

# (e) Design for Recycling of Plastic Packaging

Plastic packaging must be designed to facilitate effective recycling. Table 7 lists materials and components that must not be present in packaging equipment. Toothpaste tubes, pumps, and aerosol containers are exempt from this requirement.

Table 7: Materials and components excluded from use in packaging materials.

	and components excluded from use in packaging materials.	
Packaging Material	Excluded Materials and Components <sup>27</sup>	
	- PS labels or sleeve labels used with PET, PP, or HDPE bottles	
	- PVC labels or sleeve labels used with PET, PP, or HDPE bottles	
	- PETG labels or sleeve labels used with PET bottles	
	- Sleeve labels made from a polymer different than that of the	
	bottle	
Label or Sleeve Label	- Metallized or shrink-sleeve labels welded to the container body	
	(in-mold labeling)	
	- Other plastic materials with a density >1 g/cm <sup>3</sup> used for	
	sleeve/labels on PET packaging	
	- All other plastic materials used for sleeves/labels with a density	
	<1 g/cm <sup>3</sup> on PP or HDPE packaging	
	- PS caps used with PET, PP, or HDPE bottles	
	- PVC caps used with PET, PP, or HDPE bottles	
	- PETG caps and/or cap materials with a density greater than 1	
	g/cm <sup>3</sup> used with PET bottles	
Con	- Metal, glass, EVA caps	
Cap	- Caps made of silicone. Exceptions: silicone caps with a density	
	<1 g/cm³ used with PET bottles and silicone caps with a density	
	>1 g/cm <sup>3</sup> used with PP or HDPE bottles.	
	- Metallic foils or seals that remain fixed on the bottle or cap after	
	opening.	

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<sup>&</sup>lt;sup>27</sup> EVA: Ethylene Vinyl Acetate, EVOH: Ethylene Vinyl Alcohol, HDPE: High-Density Polyethylene, LDPET: Low-Density Polyethylene Terephthalate, PET: Polyethylene Terephthalate, PETC: Crystalline Polyethylene Terephthalate, PP: Polypropylene, PS: Polystyrene, PSL: Pressure-Sensitive Label, PVC: Polyvinyl Chloride

Packaging Material	Excluded Materials and Components <sup>27</sup>		
Barrier Coatings	- Polyamide, EVOH, Functional polyolefins, metallized and light-blocking barriers		
Materials derived from animals or produced by animals (e.g., leather, silk) must not be used as packaging materials.			

#### **Assessment and Verification:**

The applicant must submit a signed declaration of conformity indicating the composition of the packaging material (including a sample of the primary packaging, cap, label/sleeve label, adhesives, cap, and barrier coating), supported by documentation from the manufacturer.

In addition, the applicant must comply with the requirements set out in the following articles of the "Regulation on the Control of Packaging Waste," published by the Ministry of Environment, Urbanization and Climate Change in the Official Gazette dated 26.06.2021 and numbered 31523:

- Articles 12, 14, and 15 concerning packaging production and placing on the market,
- Article 13 regarding heavy metal concentrations,
- Articles 19, 20, 21, and 22 concerning recycling/recovery.

The provisions regarding waste descriptions, recovery processes, and disposal methods stated in the Annexes of the relevant Regulation must also be taken into account.

#### **Criterion 7. Waste Management**

The applicant must prepare a Waste Management Plan covering the management of all waste and residuals generated throughout the entire life cycle of the product, from raw material procurement to market release. The Waste Management Plan must start with purchasing preferences aimed at waste prevention and include planned improvement actions for each year.

For each type of waste in the facility, the associated processes and activities, annual collected waste quantities, distribution of total waste by recovery and disposal, and justifications for disposal must be documented. Future recovery targets should also be specified. Separable waste types such as cardboard, paper, and glass must be collected separately and sent to licensed recycling facilities; only in cases where recycling is not possible should they be sent to disposal facilities.

#### **Assessment and Verification:**

The applicant must hold a basic "Zero Waste" certificate and submit the Waste Management Plan—which must comply with relevant regulations—along with official records, transport documentation, and supporting materials in the application file.

In accordance with the Waste Management Regulation published by the Ministry of Environment, Urbanization and Climate Change in the Official Gazette dated 02.04.2015 and numbered 29314, the prevention, reduction, reuse, recycling, and recovery of waste, as well as its final disposal and post-disposal control and monitoring, must be carried out. Accordingly, the Waste Management Plan should include long-term policies to ensure environmentally sound waste management.

In line with the Regulation on the Control of Packaging Waste, published in the Official Gazette dated 26.06.2021 and numbered 31523, preventing the generation of packaging waste, and where unavoidable, ensuring its reuse, recycling, recovery, or use as an energy source, is essential for conserving natural resources and promoting sustainable development goals.

Waste must be collected separately following the examples provided in Annex 5 of the Zero Waste Regulation published in the Official Gazette dated 12.07.2019 and numbered 30829. The monitoring and operation of the zero waste management system should be conducted in line with the Ministry's implementation guide for enterprises, together with existing waste management systems.

# Criterion 8. Organic and Natural Content

#### (a) Organic Content

If the product carries an "organic" claim, at least 95% of the physically processed agricultural ingredients (PPAIs) that make up the product must be derived in accordance with organic farming principles. If no "organic" claim is made on the product, it is exempt from this criterion. The relevant percentage of organic ingredients is calculated as follows:

% of Organic PPAI = 
$$\sum \left[ \frac{(total\ organic\ PPAI\ amount)}{(total\ PPAI\ amount)} \right] \times 100$$

For soaps that carry an "organic" claim and contain soap noodles derived from vegetable oils among their ingredients, at least 95% of the total physically processed agricultural ingredients (PPAIs) and chemically processed agricultural ingredients (CPAIs) must be sourced in accordance with organic farming principles. The relevant percentage of organic ingredients is calculated as follows:

% of Organic PPAI and CPAI = 
$$\sum \left[ \frac{(total\ organic\ PPAI\ amount) + (total\ organic\ CPAI\ amount)}{(total\ PPAI\ and\ CPAI\ amount)} \right] x$$

100

At least 20% of a final product bearing an "organic" claim must be derived in accordance with organic farming principles. The relevant organic content percentage is calculated as follows:

# % of Organic Content (product) =

 $\left[\frac{\Sigma\left(organic\ PPAI\ amount\ of\ each\ ingredient\right) + \Sigma\left(organic\ CPAI\ amount\ of\ each\ ingredient\right)}{(total\ ingredient\ amount)}\right] \ge 100$ 

#### **Assessment and Verification:**

The applicant must submit a declaration confirming that at least 95% of the physically processed agricultural ingredients (and chemically processed agricultural ingredients, if applicable) in the product, and at least 20% of the final product itself, have been obtained in accordance with organic farming principles, including the relevant calculations.

For organic content percentages, the applicant must provide documentation in accordance with internationally recognized standards TS ISO 16128-1/ISO 16128-1 and ISO 16128-2, based on Article 4(f) of the Cosmetics Law No. 5324 dated 24.03.2005 and Articles 14, 17, and 22 of the Cosmetics Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184, as referenced in Article 7 of the "Guidance Document for Responsible Persons and End Users of Cosmetic Products," administered by the Ministry of Health, Turkish Medicines and Medical Devices Agency.

Additionally, the applicant must provide documentation regarding organic ingredients and products from a certification body accredited and listed under the "Control and Certification Bodies – Operator Lists" section of the Ministry of Agriculture and Forestry's official website<sup>28</sup>.

#### (b) Natural Content

Natural content refers to the ingredients of plant, mineral, marine, and/or animal origin included in the product formulation. If the product does not carry a "natural" claim, it is exempt from this criterion. For products that do carry a "natural" claim, the relevant percentage of natural content is calculated as follows:

<sup>&</sup>lt;sup>28</sup> https://www.tarimorman.gov.tr/Konular/Bitkisel-Uretim/Organik-Tarim

# % of Natural Content (product) =

(final product weight) — (total weight of non—natural origin ingredients) — (total weight of petrochemical ingredients)

(total weight of all ingredients)

x 100

#### **Assessment and Verification:**

The applicant must submit a declaration confirming that the natural content in the product formulation has been properly calculated, along with the calculation results.

For natural content percentages, the applicant must provide documentation in accordance with internationally recognized standards TS ISO 16128-1/ISO 16128-1 and ISO 16128-2. This documentation must be prepared in line with Article 4(f) of the Cosmetics Law No. 5324 dated 24/03/2005 and Articles 14, 17, and 22 of the Cosmetics Products Regulation published in the Official Gazette dated 08/05/2023, as referenced in Article 7 of the "Guidance Document for Responsible Persons and End Users of Cosmetic Products," administered by the Ministry of Health, Turkish Medicines and Medical Devices Agency.

In obtaining natural ingredients, compliance must also be ensured with Article 56 of the Constitution of the Republic of Turkey No. 2709 dated 09/11/1982 and Article 9 of the Environmental Law No. 2872 dated 11/08/1983, as well as with all relevant legal requirements related to flora, fauna, and wildlife—including protected species—under international agreements to which Turkey is a party, such as the CITES Convention, the Ramsar Convention, and the Convention on Biological Diversity.

# Criterion 9. Fitness for Use

A cosmetic product placed on the market must be safe for human health when used under normal or reasonably foreseeable conditions, or when used according to the recommended usage conditions based on the product's presentation, labeling, instructions for use and disposal, or any other information provided by the responsible person, in accordance with Article 5 of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184 (Repeated).

When testing the product's fitness for use, the provisions of Articles 5, 11, and 15, and Annex1 of the Cosmetic Products Regulation must be considered, as well as the "Guideline on the
Analysis of Cosmetic Products" and the "Guideline on the Safety Assessment of Cosmetic
Products" issued by the Ministry of Health, Turkish Medicines and Medical Devices Agency.
For products containing organic ingredients, traceability of raw material suppliers must be

ensured and monitored. In addition, prior to awarding the environmental label, a plan must be prepared by the competent authority to monitor compliance with these requirements.

#### **Assessment and Verification:**

The applicant must comply with the obligations stated under Articles 4(c), (d), and (e) of the Cosmetics Law No. 5324, published in the Official Gazette dated 30.03.2005 and numbered 25771.

To demonstrate product efficacy, the applicant must document analysis results in accordance with the standards 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, and TS 5822-6 ISO 5725-6, as indicated in Article 6 of the "Guideline on the Analysis of Cosmetic Products", and in line with the requirements of Chapter Four of the Cosmetic Products Regulation dated 08.05.2023.

Claims regarding the marketed product may be supported by best practices, including but not limited to experimental studies such as in silico, in vitro, and ex vivo methods; instrumental or biochemical methods; studies conducted on volunteers (e.g., efficacy and safety studies); investigator assessments; and sensory evaluations, in line with Article 11(2) of the "Guideline on Claims for Cosmetic Products".

The applicant must also submit a declaration indicating that the product is fit for use under the applicable legislation. Additionally, a compliance monitoring plan must be submitted, detailing the number and types of products under the license, and ensuring ongoing conformity to the criteria with appropriate levels of documentation. This plan must also indicate whether the license holder is involved with another manufacturer or supplier, contract manufacturing, wholesale/retail supply, or brand ownership agreements.

#### Criterion 10. Information to Be Provided on the Ecolabel

The environmental label must be placed on the product packaging in a size of 2x2 cm. Below the label, the following statement must appear in 6-point font or a legible size:

"The use of the environmental label on this product has been approved by the Ministry of Environment, Urbanization and Climate Change of the Republic of Türkiye under the Environmental Label Regulation published in the Official Gazette dated 19.10.2018 and numbered 30570, due to its environmental performance."

In addition, labeling requirements under Article 22 of the Cosmetic Products Regulation published in the Official Gazette dated 08.05.2023 and numbered 32184 (Repeated) must be followed.

If approved during the application process, the following claims may also be included:

- Reduced impact on aquatic ecosystems
- Environmentally friendly production
- Environmentally conscious packaging

For organically and/or naturally certified products, the percentage of organically derived ingredients based on the total product weight must be stated on the packaging as:

"X% organic/natural" or "X% certified organic/natural".

If the product contains any nanomaterials/particles, this must be clearly indicated, with the term "nano" placed in parentheses after the name of each such substance.

The product must also be accompanied by appropriate usage instructions to maximize performance and minimize waste generation. These instructions must include information on reuse, recycling, and/or correct disposal of the packaging. Additionally, the packaging must include the following statement:

"Always use the appropriate amount for maximum efficiency and minimum environmental impact."

#### **Assessment and Verification:**

The applicant must provide a signed declaration of conformity along with a sample of the packaging on which the environmental label is affixed. The environmental label must appear on the packaging of different product sizes in the dimensions determined by the Ministry of Environment, Urbanization and Climate Change.

# ANNEX I. PRODUCT TYPES WITHIN THE PERSONAL CARE PRODUCT GROUP

Rinse-off	Leave-on
A. SKIN CAR	E PRODUCTS
A.1.1. Skin care products excluding face	A.1.1. Skin care products excluding face masks
masks A.1.2. Face mask	A.1.2. Face mask
A.1.3. Eye contour products	A.1.3. Eye contour products
A.1.5. Hand care products	A.1.4. Lip care products
A.1.6. Foot care products	A.1.5. Hand care products
A.1.7. Body care products	A.1.6. Foot care products
A.1.8. External genital area care products	A.1.7. Body care products
A.1.9. Chemical exfoliating products	A.1.8. External genital area care products
A.1.10. Mechanical exfoliating products	A.1.9. Chemical exfoliating products
A.1.12. Other skin care products	A.1.10. Mechanical exfoliating products
A.2.1. Soap	A.1.12. Other skin care products
A.2.2. Bath/shower products	A.2.3. Make-up remover products
A.2.3. Make-up remover products	A.2.4. External genital area cleansing products
A.2.4. External genital area cleansing products	A.2.5. Other skin cleansing products
1	A 5 1 Antinovanirant products
A.2.5. Other skin cleansing products A.5.1. Antiperspirant products	A.5.1. Antiperspirant products A.5.2. Non-antiperspirant deodorant products
A.6.1. Shaving products	A.6.1. Shaving products
A.6.2. Pre-/post-shaving products	A.6.2. Pre-/post-shaving products
	A.6.3. Other pre-/post-shaving products
A.6.3. Other pre-/post-shaving products	A.9.1. Pre-sun and after-sun products
A.10.1. Other skin products	1
	A.9.2. Sun protection products A.10.1. Other skin products
D HAID AND SC	CALP PRODUCTS
B.1.1. Shampoo	B.1.1. Shampoo
B.1.2. Hair conditioner	B.1.2. Hair conditioner
B.1.3. Scalp and hair follicle care products	B.1.3. Scalp and hair follicle care products
B.1.4. Anti-dandruff products	B.1.4. Anti-dandruff products
B.1.5. Anti-hair loss products	B.1.5. Anti-hair loss products
	B.1.6. Other hair and scalp care and cleansing
cleansing products	products
B.4.2. Other hair and scalp products	B.4.1. Hair sun protection products
B.4.2. Other half and scarp products	
C NAIL AND CHI	B.4.2. Other hair and scalp products
	C.2.1. Nail products
C.2.1. Nail products	C.2.1. Ivan products
C.2.3. Other nail care/nail strengthening products	C.2.2. Nail strengtheners
C.4.3. Other nail and cuticle products	C.2.3. Other nail care/nail strengthening products
	C.4.1. Cuticle removers/softeners
	C.4.2. Nail restructuring products C.4.3. Other nail and cuticle products
D ODAL CADE AND	HYGIENE PRODUCTS
D.1.1. Toothpaste	D.1.3. Other dental care products
D.1.2. Tooth cleaning powder/salt	D.2.2. Breath freshening sprays/mouth sprays
D.1.3. Other dental care products	D.2.3. Other mouthwashes/breath freshening sprays/mouth sprays

Rinse-off	Leave-on
D.2.1. Mouthwashes	D.4.1. Other oral care and hygiene products
D.2.3. Other mouthwashes/breath freshening	
sprays/mouth sprays	
D.4.1. Other oral care and hygiene products	