NOTE

Royal Decree 1599/1997, of October 17, on cosmetic products. Second additional provision. Personal hygiene (or personal care) products.

https://www.boe.es/eli/es/rd/1997/10/17/1599/con

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1. Personal hygiene products shall be understood to mean all substances or preparations that do not fall under the legal definition of cosmetics, biocides, medical devices or medicines, are intended to be applied to the skin, teeth or mucous membranes of the human body for the purpose of hygiene or aesthetics, or to neutralize or eliminate ectoparasites, such as dentifrices, beauty products, pediculicides (head lice treatments), vaginal moisturizers, anal cleansers for haemorrhoids, sports massage products, nasal sprays or eye drops, or any other product that can be qualified as such.

2. Definitions and explanations

a) Dentifrices: substances or preparations that are applied to the buccal mucosa (the inside of the mouth) and / or to the teeth that, due to their indications, composition or form of presentation, cannot be considered cosmetic, such as toothpastes, mouthwashes, tooth whitening agents, chewing gum or tablets for oral hygiene or hyper fluoridated products for professional use or any other product that may be qualified as such.

GRS note: these products can still be considered to be cosmetics (chewing gum is borderline food/cosmetic) provided the product meets the definition set out in Art. 2 of Regulation 1223/2009 i.e. with a view exclusively or mainly to cleaning, perfuming, changing appearance, protecting, keeping in good condition or correcting body odours. Where the primary purpose goes beyond those functions, for example preventing cavities, gingivitis, tooth sensitivity, etc. ... the product will be classified among personal care products.

Another example of a factor that plays an important role in the case of dentifrices is the presence of fluoride (total F concentration must not exceed 0,15 % - Annex III). Cosmetics Regulations limit the use of that substance in cosmetics. Personal hygiene products are not restricted by this limitation, and can contain higher concentrations as authorised by the Agency (AEMP) on a case-by-case assessment.

b) Aesthetic products: the products of application on the skin, which do not have the legal consideration of cosmetics, medicines or health products because of their composition, indications, mechanism of action, application or duration, such as, where appropriate, inks for tattoos, micro pigments or preparations intended for permanent and semi-permanent makeup, chemical skin abrasion masks or transdermal patches, or any other product that can be qualified as such.

3. The products mentioned in this additional provision will be subject to commercial authorisation granted by the Spanish Agency of Medicines and Health Products, to be recorded in the registry established by the Agency.

4. The authorisation procedure for these products will be adjusted, as appropriate, to the provisions of article 9 (special declarations). This authorisation will, however, be valid for five years and may be revalidated at the request of the person responsible for placing it on the market in the last semester/ period of its term.

5. The Spanish Agency for Medicines and Health Products may require the trials, data or tests it deems necessary toxicologically to evaluate the product, as an extension of the assessment of safety for human health established in Article 6.d).

6. The provisions of Articles 4, 11, 12, 13, 16, 18, 19, 20 and 21 shall apply to the aforementioned products, where appropriate.

7. The labeling of these products will be regulated, as appropriate, by article 15, which will also incorporate the health registration number and the quantitative composition of the active components, where appropriate. Depending on the nature of each product, the Spanish Agency for Medicines and Health Products may require the inclusion in the labeling of the statements or data deemed appropriate for the correct use of the product and the prevention of risks.

8. The Spanish Agency for Medicines and Health Products may, when the nature of the product so requires, limit its use to certain professional sectors.
9. The Spanish Agency for Medicines and Health Products will decide on the inclusion of a specific product in the aforementioned registry, depending on its specific characteristics.

10. The manufacturers and / or importers of these products must be specifically authorised to carry out manufacturing activities and / or importation of these products, which will be reflected in the corresponding authorisation of activities, except for the pharmacies that produce these products for their dispensation in their own offices.