

## **Information Circular**

**INFARMED - National Authority for Medicines and Health Products, I.P.**

**Subject: Use of cannabis and its derivatives in cosmetic products**

### **General Framework**

Cannabis is classified in the (Portuguese) national territory as a narcotic, and it is included in table I-C, annexed to Portuguese Decree-Law No. 15/93, of 22 January, in its current wording.

Within this framework, the use of the cannabis plant for purposes other than medicinal is prohibited, except for the use of fibers (stems) and seeds of low-THC varieties of cannabis for industrial purposes (hemp)<sup>1</sup>.

Preparations based on the cannabis plant for medicinal purposes are subject to authorization to be placed on the market, in accordance with the provisions of Decree-Law No. 8/2019 classified as special medical prescription.

Pursuant to the provisions of Decree-Law no. 15/93, of 22 January, Regulatory Decree no. 8/2019, of January 15th, and Ordinance no. 83/2021, of April 15th, is the responsibility of INFARMED, I.P. authorize the cultivation, manufacture, wholesale trade, import and export of medicinal products, preparations and substances based on the cannabis plant, solely and exclusively for medicinal, medical-veterinary and scientific research purposes, regardless of the THC content.

With regard to the various cannabinoids that form part of the cannabis resin, and in particular the substance cannabidiol (CBD), it is the express understanding of the International Narcotic Control Body<sup>2</sup> (INCB), that it is covered by the Single Convention on Narcotic Drugs of 1961, as an extract / preparation of the cannabis plant, which is included in Table I annexed to the aforementioned convention

Thus, the aforementioned substances, namely the substance cannabidiol (CBD), as a resin or cannabis preparation, are included in Table I-C, attached to Decree-Law no. subject to the control measures applicable to the substances provided for therein.

### **Cosmetic Products**

The placing on the market of cosmetic products complies with the requirements established by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009.

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<sup>1</sup> article 28(2) of the 1961 Single Convention on Narcotic Drugs.

<sup>2</sup> United Nations body, created by the 1961 Convention, responsible for controlling and monitoring compliance with the Single Conventions on Narcotic Drugs and Psychotropics, by the Signatory States thereof, cfr. Decree-Law No. 435/70, of 12 August, which approves, for ratification, the Single Convention of 1961 on Narcotic Drugs.

This Regulation prohibits the inclusion in cosmetic products of all substances listed in tables I and II of the Single Convention on Narcotic Drugs of 1961<sup>3</sup>, through entry 306 of Annex II. Additionally, at a national level, these substances are considered controlled, in accordance with the provisions of Decree-Law no. 15/93 of 22 January, in its current wording.

Cosmetic products cannot therefore contain the following substances/preparations related to the cannabis plant, regardless of their tetrahydrocannabinol (THC)<sup>4</sup> content:

- *Cannabis* and *Cannabis* resin;
- *Cannabis* extracts and tinctures;
- Leaves and flowering/flowering or fructified leaves of the *Cannabis* plant;

The inclusion of CBD or other cannabinoids, which exist naturally in the cannabis plant, is not allowed, as they are obtained through the preparation of extracts or tinctures of *Cannabis* or its resin.

Included in this ban are the substances “CANNABIDIOL - DERIVED FROM EXTRACT OR TINCTURE OR RESIN OF CANNABIS” and “CANNABIS SATIVA LEAF EXTRACT”. These designations appear in COSING<sup>5</sup> but their inclusion in cosmetic products is not authorized.

Exceptions to this prohibition are the use of substances/preparations obtained from plant seeds with a THC content of  $\leq 0.2\%$ <sup>6</sup>, such as cannabis seed oil, of varieties registered in the Common Catalogue of Varieties of Agricultural Species.

There are other sources of CBD that are not covered by Annex II of Regulation (EC) No 1223/2009, but which are under analysis in the European Union and the World Health Organization<sup>7</sup>. The use of these substances in cosmetics must be analysed on a case-by-case basis and always requires a safety assessment.

The adequacy of the composition of cosmetic products that are placed on the market to the legislation in force is an obligation of the Responsible Person<sup>8</sup> who must ensure compliance with the applicable legislation and the safety of cosmetic products under the foreseen or reasonably foreseeable conditions of use.

Responsible persons or distributors operating in Portugal must ensure that the composition of the products they make available on the market meet these requirements.

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<sup>3</sup> Convenção Única sobre os Estupefacientes “Single Convention on Narcotic Drugs”, New York, 30 março de 1961

<sup>4</sup> In which industrial hemp varieties are included.

<sup>5</sup> CosIng is the European Commission's database for information on substances and ingredients. An ingredient listed on CosIng does not mean that its use in cosmetic products is approved.

<sup>6</sup> As provided for in Ordinance No. 83/2021, of April 15, in its current wording.

<sup>7</sup> <https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf>

<sup>8</sup> Artigo 4º do Regulamento (CE) n.º 1223/2009 do Parlamento Europeu e do Conselho de 30 de novembro de 2009.