

**From:** [REDACTED] (GROW)  
**To:** "xxxx@xxxxxxxxxx.xx"  
**Cc:** [REDACTED] (GROW)  
**Subject:** Ares(2019)2922103 - RE: Cannabidiol for cosmetics  
**Date:** mardi 7 mai 2019 11:38:22  
**Attachments:** image001.png

Dear Mr. [REDACTED],

Thank you for your query.

The disclaimer you are making reference to ([http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details\\_v2&id=93486](http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=93486)) reflects the text of the Single Convention on Narcotics.

Entry 306 of Annex II to the Cosmetics Regulation 1223/2009 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1493906428740&uri=CELEX:32009R1223>) refers to "Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961".

Schedules I and II of the Convention are lists of drugs. According to Art. 1 "definitions" of the convention, "Drug" means any of the substances in Schedules I and II, whether natural or synthetic.

The list of drugs in Schedule I (Schedules as at 16 May 2018: <http://undocs.org/ST/CND/1/Add.1/Rev.4>) includes: CANNABIS and CANNABIS RESIN and EXTRACTS and TINCTURES OF CANNABIS.

Article 1 of the convention defines these terms as follows:

(b) "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.

(c) "Cannabis plant" means any plant of the genus Cannabis,

(d) "Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.

Based on the above, ingredients derived from cannabis to the extent that they fall within the scope of the 1961 Convention should be banned in cosmetic products based on entry 306 of Annex II of the Cosmetics Regulation. According to the WHO ECDD critical review (<http://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf>), cannabidiol 'is one of the naturally occurring cannabinoids found in cannabis plants. It is a 21-carbon terpenophenolic compound which is formed following decarboxylation from a cannabidiolic acid precursor, although it can also be produced synthetically'.

Cannabidiol is not included as such in the Schedules of the Single Convention on Narcotic Drugs of 1961. Therefore, we consider Cannabidiol outside the scope of entry 306 of Annex II to the Cosmetics Regulation 1223/2009 (CosIng entry on Cannabidiol - Synthetically Produced). However, if it is prepared from banned substances such as extracts or tinctures or resin of Cannabis Cannabidiol would fall under the scope of the Convention and the prohibition II/306 should apply.

Please note that according to Article 4 of the Cosmetics Regulation (EC) No. 1223/2009 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1553184062206&uri=CELEX:02009R1223-20180801#E0027>) it is up to the responsible person to ensure that a product complies with the relevant legal obligations ("For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation"). Furthermore, according to Article 3 "A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use". Therefore, we would kindly ask you to reflect on the definitions of the Single Convention carefully and the respective prohibitions in the Cosmetics Regulation.

The views expressed in this email are not legally binding; only the Court of Justice of the EU can give an authoritative interpretation of Union law.

We hope you will find this information useful.

kind regards,

[REDACTED], PhD

[REDACTED]



**European Commission**

DG for Internal Market, Industry, Entrepreneurship and SMEs  
 Unit D4 – Health Technology and Cosmetics

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**From:** Heaven Hemp Srls

**Sent:** Monday, April 29, 2019 10:40 AM

**To:** GROW D4

Cc: [REDACTED] (GROW) ; [REDACTED] (GROW)

**Subject:** Cannabidiol for cosmetics

**Importance:** High

Dear European Commission - Cosmetic Office,

We are writing in the way to clarify what is specify on the document in the following link:

After a review of the cosmetic restrictions, it is written on the document that any cosmetic product prepared as an extract or tinctures or resin of Cannabis are restricted.

Because so, since you are clarifying that Cannabidiol synthetically produced can be used as ingredient, We are worry about to understand if purified and isolate CBD can be considered as synthetically produced.

Please, we ask you to have this answer as soon as possible in the way to understand how we can proceed with our project on using CBD on cosmetics.

Thank you very much.

Regards,

[REDACTED]

Heaven Hemp srls

Via Ripoli, snc

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Da [REDACTED] [@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)

A [info@heavenhemp.it](mailto:info@heavenhemp.it)

Cc [REDACTED] [@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)

Data Wed, 9 Jan 2019 15:33:52 +0000

Oggetto Ares(2018)6034021 - RE: Information about registration of Canapa Sativa Cosmetic Products

Dear Mr. [REDACTED]

Thank you for your query.

According to the Cosmetics Regulation (EC) No 1223/2009, all cosmetic products placed on the EU market must be safe for human health. It is the responsibility of the manufacturer (or the importer) as "responsible person" defined in Article 4 of the Cosmetics Regulation to ensure the safety of the product. Consequently, recommending ingredient concentrations falls outside the remit of the Commission services. For more information concerning risk assessment and safety, we would kindly suggest to follow the experimental approaches/methods described in the SCCS Notes of Guidance (Version 10th).

You can find it here:

[https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_224.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf)

Please note that the attached document ("*MGC Derman EU cosmetic approval*") that you provided, contains a great number of inconsistencies and ambiguities in the way it interprets the Cosmetic Regulation and CPNP. We would therefore suggest to read carefully the Cosmetics Regulation (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1542120956521&uri=CELEX:02009R1223-20180801>), before placing a product on the market. In addition, you can find more information about the CPNP functioning (user's manual), following this link

([http://ec.europa.eu/growth/sectors/cosmetics/cpnp\\_en](http://ec.europa.eu/growth/sectors/cosmetics/cpnp_en)).

Kind regards

[REDACTED], PhD

[REDACTED]



**European Commission**

DG for Internal Market, Industry, Entrepreneurship and SMEs

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**From:** GROW COSMETICS AND MEDICAL DEVICES  
**Sent:** Friday, November 23, 2018 5:50 PM  
**To:** [REDACTED] (GROW)  
**Subject:** FW: Information about registration of Canapa Sativa Cosmetic Products  
**Importance:** High

**From:** info <[info@heavenhemp.it](mailto:info@heavenhemp.it)>  
**Sent:** Friday, November 23, 2018 5:42 PM  
**To:** GROW D4 <[GROW-D4@ec.europa.eu](mailto:GROW-D4@ec.europa.eu)>  
**Subject:** Information about registration of Canapa Sativa Cosmetic Products  
**Importance:** High

Dear Directorate General for Internal Market, Industry, Entrepreneurship and SMEs - European Commission,

We are a little Start-Up Italian Company that cultivate Canapa Sativa L. EU registered varieties.

Since We are trying to understand the marketing, We were looking for information through the internet in the way to evaluate different possibilities.

We get some information that you may find attached that talks about a Cosmetic company that have place Cannabidiol (CBD) into the EU Market as cosmetic product after the approval of the EU Commission.

Since our interest is big for this notice, We was wondering how much Cannabidiol are allowed on each Cosmetic product.

We would like to produce Body balm or Body cream for skin conditioning and protecting.

Also, I Linked you the information that you may find in CosIng regarding cannabidiol:

[http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?  
fuseaction=search.details\\_v2&id=93486](http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=93486)

Please, We appreciated your time and We thank you very much for your help.

Kind regards,

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