



From: [REDACTED] (GROW)
To: [REDACTED]
Cc: [REDACTED] (GROW)
Subject: Ares(2018)4672777- RE: Ares(2018)4123138 - RE: Cosmetic Compliance Questions - Hemp Seed Oil
Date: mercredi 9 janvier 2019 12:21:37
Attachments: [image001.png](#)
[image002.png](#)

Dear Mrs. [REDACTED],

Thank you for your follow-up question.

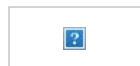
Please note that the Cosmetics Regulation (EC) 1223/2009 makes reference to schedules/tables laid out in the single Convention on narcotic drugs signed in New York on 30 March 1961. Our regulation does not refer to the THC content of ingredients.

We would kindly reiterate that 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. It is for the national authorities to verify whether the cosmetic products in question comply with the rules on safety.

We hope you find this information helpful.

Kind regards

[REDACTED], PhD



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

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From: [REDACTED]@bitebeauty.com>
Sent: Tuesday, September 11, 2018 6:14 PM
To: [REDACTED]@ext.ec.europa.eu>
Cc: [REDACTED] (GROW) [REDACTED]@ec.europa.eu>
Subject: RE: Ares(2018)4123138 - RE: Cosmetic Compliance Questions - Hemp Seed Oil

Good afternoon Mr. [REDACTED],

Thank you for your response: I have reviewed what was provided, and all the associated Schedules.

Based on the below criteria, as well as the limitations on the THC content laid out in *Article 32(6) and in Article 35(3) of Regulation (EU) No 1307/2013*, stating in Section 6: "...Areas used for the production of hemp shall only be eligible hectares if the varieties used have a tetrahydrocannabinol content not exceeding 0,2 %."

The Home Office Controlled Drugs Information

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/674713/Factsheet-_Cannabis_CBD_and_Cannabinoids- January_2018.pdf) also lists the same limit of 0.2% THC, and states that Cannabis Sativa Seed Oil is allowed to be used for commercial production (such as an ingredient in a cosmetic), as long as it meets these requirements.

Therefore, if the Cannabis Sativa Seed Oil (which is the INCI name for the ingredient that we are using) meets all the criteria set out in the regulations that you provided below, as well as the THC limits described in the Schedule I and II, can you confirm if it would be an acceptable ingredient to use in a cosmetic formulation?

We will of course be going through our Safety Assessor for a full report, but I wish to confirm that the ingredient itself and its INCI name are acceptable to use in a cosmetic product being registered in the EU, as long as it meets the described conditions and THC levels.

Thank you for your clarification on this issue.

From: [REDACTED] <[REDACTED]@ext.ec.europa.eu> <[REDACTED]@ext.ec.europa.eu>
Sent: September-11-18 10:22 AM
To: [REDACTED] <[REDACTED]@bitebeauty.com>
Cc: [REDACTED] <[REDACTED]@ec.europa.eu>
Subject: Ares(2018)4123138 - RE: Cosmetic Compliance Questions - Hemp Seed Oil

Dear Mrs. [REDACTED]

Thank you for your query.

Please note that the CosIng database has no legal value and the information provided (i.e references) have informative purpose.

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.

We would also like to remind you that regarding the safety of cosmetic ingredients, 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. To this end, a product information file which contains the information required under Article 11 of the Cosmetics Regulation must be kept readily available to the competent authorities of the EU member state concerned.

The Member States are responsible for monitoring compliance with the rules laid down in the Cosmetics Regulation via in-market controls of the cosmetic products made available on the market (Art. 22 of the Cosmetic Regulation No 1223/2009). These controls are based on appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples.

Therefore, it is for national authorities to verify whether the cosmetic products in question comply with the rules on safety.

Please note that 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.

Best regards,

From: [REDACTED] <[REDACTED]@bitebeauty.com>
Sent: Friday, August 03, 2018 6:39 PM
To: GROW D4
Subject: Cosmetic Compliance Questions - Hemp Seed Oil
Importance: High

Good Afternoon,

We have a rather urgent question about the Annex II/306.
We want to use Hemp Seed Oil in one of our products, but we see that there is an entry on Annex II listing it as a narcotic.

There are other entries on COSIng that list Hemp Seed Oil that appear to be acceptable, and there are product being sold in the EU that contain this ingredient.

Can you please let me know what the criteria is to be able to use Hemp Seed Oil in lipstick products, any any tests that need to be done or test methods that are acceptable to the EU?

Thanks!



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