From: \_\_(GROW

To: \_\_\_(GROW)

Subject: Ares(2018)5900258 - RE: Ares(2018)5714834- RE: question on annex ii of cosing of specific substance

Date: lundi 26 novembre 2018 15:33:40

Attachments: image001.png image002.png

Dear Ms. ,

Thank you for your follow-up question. There are ongoing internal discussions on the Cannabis sativa ingredients and at the moment I can only provide you with a the following information:

The CosIng database is an inventory of cosmetic substances and ingredients, <u>employed for labelling</u> cosmetic products throughout the EU. The ingredient assigned with an INCI name that appears in the inventory section of CosIng <u>does not mean it is to be used in cosmetic products nor approved for such use.</u>

Entry 306 of Annex II of 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: <a href="http://undocs.org/ST/CND/1/Add.1/Rev.4">http://undocs.org/ST/CND/1/Add.1/Rev.4</a>) 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 like to remind you that regarding the safety of cosmetic ingredients, all cosmetic products placed on the EU market <u>must be safe for human health</u>. It is the <u>responsibility of the manufacturer (or the importer) as "responsible person" defined in Article 4 of the <u>Cosmetics Regulation to ensure the safety of the product</u>. 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.</u>

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.

Concerning the CPNP platform, Article 13 of the Cosmetics Regulation (EC) No 1223/2009 requires that prior to placing cosmetic products in the EU market, the responsible persons and, under certain circumstances, the distributors of cosmetic products shall notify through CPNP about the products they place or make available on the European market, by submitting information through the CPNP. Some of these information is then made available electronically to the Competent Authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information) and to the Poison Centres, or similar bodies established by Member States (for the purposes of medical treatment).

CPNP is a free online notification system created for the implementation of the Cosmetics Regulation (EC) No 1223/2009 and "acts" as an online registry.

According to the "User manual ART.13" (https://webgate.ec.europa.eu/cpnpro/main/?

event=main.document.getUserManual&docid=1&Ing=EN): "It is important to note that the fact that a product has been successfully notified through CPNP does not necessarily mean that the product in question fulfils all the requirements of the Regulation (EC) N° 1223/2009 of the European Parliament and of the Council on cosmetic products." (i.e The notification of cosmetic products through the CPNP is not equal to authorization. The national competent authorities are responsible to check whether a product complies with the rules laid down in the Cosmetics regulation). In the Appendix of the "User manual ART.13" under the tittle "Rules on Specific Ingredients of Concern and/or pH Values", you can find more information about the ingredient that might be of concern in the CPNP portal, however this appendix does not substitute the Annexes of the Cosmetics Regulation (EC) No 1223/2009.

We hope you will find this information useful.

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.

Best regards,

, PhD

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

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@beautylab.gr> From: Sent: Friday, November 16, 2018 2:37 PM

(GROW) To: @ec.europa.eu>

(GROW) @beautylab.gr> Cc: @ec.europa.eu>;

Subject: RE: Ares(2018)5714834- RE: question on annex ii of cosing of specific substance

Dear Mr.

in reference to the legal status of cannabis sativa seed oil , I would appreciate if I could have your feedback on legal entity of cannabis sativa seed oil, taking in consideration below issues:

1.EU legislation for cannabis do not forbid the use of it in cosmetics, reference : http://www.emcdda.europa.eu/system/files/publications/4135/TD0217210ENN.pdf

2.cannabis sativa seed oil Has been added to Anexx II/306 of 1223/2009

306 Narcotics, natural and vnthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961

but if you overthrow to the table that the point 306 of annex ii prescribe , there is reference for specific cannabis substitutes and THC that is substitute in cannabis sativa seed oil is not included to this EU decision, reference https://eurlex.europa.eu/legal-content/EL/TXT/PDF/?uri=CONSIL;ST\_6084\_2018\_INIT&gid=1541514298125&from=en.),

3.During the product disclosure in CPNP platform and more specific if you add on relative field the ingredients of the formula one by one, cannabis sativa does not appeared as prohibited raw material.

As a results of all above we would like to have an official opinion for the use of cannabis sativa seed oil with cas number 89958-21-4 in cosmetics.

Looking forward for your feedback.

With my kind regards

Regulatory Department

Cosmetic Consulting & Packaging Services 22, Davaki Str., Pefki

15121 Athens, Greece T:+ Emai @beautylab.gr

@ec.europa.eu [mailto @ec.europa.eu]

Sent: Friday, November 9, 2018 4:57 PM

To: <u>@beautylab.gr</u>

Cc: @ec.europa.eu
Subject: Ares(2018)5/14834- RE: question on annex ii of cosing of specific substance

Dear Ms.

Thank you for your query.

We would like to inform you that the Coslng database is regularly updated. Many entries concerning Cannabis-related ingredient/substances were updated in April 2018.

Please note that Cosing database is available for informative purposes and only the annexes of the Cosmetic Regulation (EC) No 1223/2009 have legal value.

We hope you find this information helpful.

Kind regards

, PhD

**European Commission** 

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

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ec.europa.eu/bienkowska

From: GROW COSMETICS AND MEDICAL DEVICES Sent: Tuesday, November 6, 2018 1:36 PM

To: (GROW) < @ec.europa.eu>

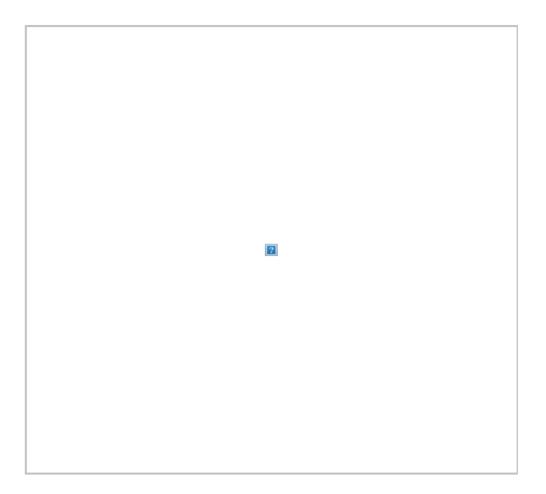
Subject: FW: question on annex ii of cosing of specific substance

From: @beautylab.gr> Sent: Tuesday, November 6, 2018 12:38 PM To: GROW D4 < GROW-D4@ec.europa.eu> ' < Cc: @beautylab.gr>

Subject: question on annex ii of cosing of specific substance

Dear Sirs,

I would appreciate if I could have your support/feedback on the date where below substance has been added in annex ii /306 on the cosing portal.



Thank you very much in advance.

With my kind regards



Regulatory Department

## Beautylab

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