

## Analytical proposal to detect prohibited theophylline in cosmetic products.

Theophylline is a molecule naturally present in small amount in plants such as tea, cocoa beans, guarana. It is a purine derivative, exactly a dimethylxanthine, quite similar to caffeine.<sup>1,2</sup>

It is used clinically for asthma therapy, but it is also recognized as a cosmetic agent with anti-age and anti-oxidative properties. In particular, it stimulates protein expression of metallothionein-1, mRNA levels of collagen I and III, and it increases levels of melatonin intracutaneously, which acts as a DNA damage repair neuromodulator.<sup>3</sup>

Following the dossier presented by the Netherlands in 2019, ECHA decided to classify Theophylline as REPRO 1B and consequently it must enter Annex II of the Cosmetic Regulation, which was made official by **REG 2023/1490 of 19/07/2023, (Omnibus Act VI), which implements ATP XVIII.**<sup>4,5,6,7</sup>

The classification has been decided as there are no sufficient data on humans to declare it is toxic for reproduction, but there are evidences on animals, although the mechanism of action is not clear.<sup>5</sup>

**Since 1<sup>st</sup> December 2023 all the cosmetic products on the market should not contain Theophylline**, as ANNEX II of REG 1223 lists the substances prohibited in finished cosmetic products. It is important to note that Theophylline is not included pure as a single molecule in cosmetic formula, but it is present in the plants extracts rich in xanthines (such as Guarana extracts, *Paullinia Cupana*, and Cocoa extracts, *Cocos Nucifera*), and it is the most important ingredients of tea extracts (*Camellia Sinensis*). So, consumers may not find Theophylline in the INCI list, nor the manufactures declare it with its INCI name, but it may be present in all the cosmetic products which contains cocoa, coffee, guarana, and tea extracts.

Manufacturers should check with their suppliers the presence of Theophylline in its raw materials, and they should check the finished cosmetic products do not contain Theophylline.



### NEOTRON PROPOSAL

Neutron performs the analysis of Theophylline by HPLC-MS/MS or HPLC-DAD techniques, according through an internal method.

Do you want to know if your cosmetic products comply with the next updating of REG 1223/2009?

Please contact us and we will be glad to give you all the information you need.

Neutron, part of the Cotecna Group, is a global player in analytical services on food and feed products, supplements, materials in contact with food (FCM), cosmetics, and pharmaceutical products.



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### References:

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