

Carbiotix achieves regulatory approval for CarbiAXOS cosmetic ingredient

Carbiotix (publ) ("Carbiotix" or the "Company") announces today that the Company has achieved regulatory approval for CarbiAXOS based on corn bran as a cosmetic ingredient. This marks the first regulatory approval for CarbiAXOS as a prebiotic ingredient, demonstrating the general safety of the product. The approval process, similar to GRAS SA, was achieved through a self-affirmation process with the assistance of a third-party regulatory consultant in the drafting of a safety dossier. This approval now opens the door to commercial activities with regards to ramping up of sales activities, the production of samples suitable for customer formulation activities, and accelerating next generation prebiotic development activities.

Erik Deaner, CEO of Carbiotix, comments:

"This approval both sends a positive message to the market and provides an enormous amount of confidence in the current regulatory timeline as we push ahead with the GRAS SA approval of multiple products. I want to congratulate the entire Carbiotix team in their efforts over the past three years to get to this point and look forward to accelerating product development, regulatory- and sales activities going forward."

Today, Carbiotix announces regulatory approval for CarbiAXOS based on corn as a cosmetic ingredient. This significant achievement demonstrates the general safety of CarbiAXOS for cosmetic applications, as well as strengthening its potential as a nutraceutical, thanks to its foundation in natural materials. Similar to the regulatory GRAS SA process, Carbiotix has worked with a third-party regulatory consultant in the drafting of the safety dossier and will continue to do so with each iteration of CarbiAXOS going forward.

Additionally, Carbiotix can now leverage its production of a cosmetic ingredient at the facility in Bjuv for global sales and distribution, optimizing the production investments previously made in the facility.

Prebiotics as cosmetic application

Prebiotics are increasingly being used in topical (wash-on / wash-off) applications as a means to improve the health of the skin microbiome. Thus, a skin prebiotic ingredient can be used for general cosmetic applications as well as potentially an adjuvant with topical therapeutics to address skin related diseases. Moreover, a skin prebiotic ingredient can be delivered together with probiotics and postbiotics in the form of a synbiotic product. Regardless of the application, the efficacy of the prebiotic is a key factor impacting its use, application, and value as a prebiotic. CarbiAXOS has been designed to be a best in class effective prebiotic that is not only suitable for nutraceutical applications but also cosmetic applications. Moreover, like nutraceutical applications, the efficacy of CarbiAXOS for cosmetic applications can be validated using the LinkGut microbiome companion diagnostic platform. The global market for cosmetic prebiotic ingredients is estimated to be roughly 10% of the 1 Billion Euro high-end prebiotic ingredients market Carbiotix is targeting, with nutraceutical applications representing the other 90% of the market. [\(1\)](#) [\(2\)](#)

CarbiAXOS has gone through several development iterations over the past three years to improve the efficacy and suitability of the product for different applications, the time to market, as well as the cost, flexibility, and environmental impact of the manufacturing process. From using an in-house production enzyme, to using a third-party enzyme and finally an iteration where the use of an enzyme is optional; this development process has resulted in new CarbiAXOS products and processes with each iteration

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impacting the regulatory process. Although, CarbiAXOS will continue to be improved over time, the Company is now pursuing the regulatory approval of the current generation of CarbiAXOS as a nutraceutical and cosmetic ingredient to demonstrate its general safety.

Forward-looking statements

This communication contains forward-looking statements, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their nature, as is research and development work in the biotechnology segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios as described in this press release.

This is information that Carbiotix AB is obliged to make public according to the EU Market Abuse Regulation (MAR). The information was made publicly available by the Company's contact person set out below on 3 November 2023.

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Carbiotix AB (CRBX) (www.carbiotix.com) is an award-winning biotechnology company pioneering microbiome healthcare through a portfolio of prebiotic modulators and diagnostic testing services.