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REDUCTION IN SWEATING BY A IONS MULTI-SUBSTITUTED PHOSPHATE BASED MINERAL INGREDIENT, AS AN EFFECTIVE ALTERNATIVE TO TRADITIONAL ALUMINUM CHLOROHYDRATES SALTS:

AN EFFICACY STUDY

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INTRODUCTION

Excessive sweating can be a problem especially for the interpersonal relationships. Sweat is odorless, but bacteria residing on skin transform its components in volatile substances responsible for the unpleasant odor[1]. Topical application of products containing aluminum chloride, chlorohydrate or sesquichlorohydrate can be irritating to the skin due to the high chloride content producing hydrochloric acid (HCl)[2].

To create a new antiperspirant and deodorizing active ingredient we started from biomimetic hydroxyapatite, a natural, physiological, mineral ingredient, useful to allow a controlled release of functional molecules and that possesses good adsorption properties.

Biomimetic hydroxyapatite is the main component of bones and teeth, shows low crystallin index, rough surface, high hydration state, high degradability and naturally occurring ions substitution[3]. These properties improve hydroxyapatite biocompatibility[4], adsorption properties, ions mobility and exchange. The natural occurring ions substitution significantly increases water and odors adsorption, thus improving the antiperspirant and deodorizing efficacy of hydroxyapatite[5].

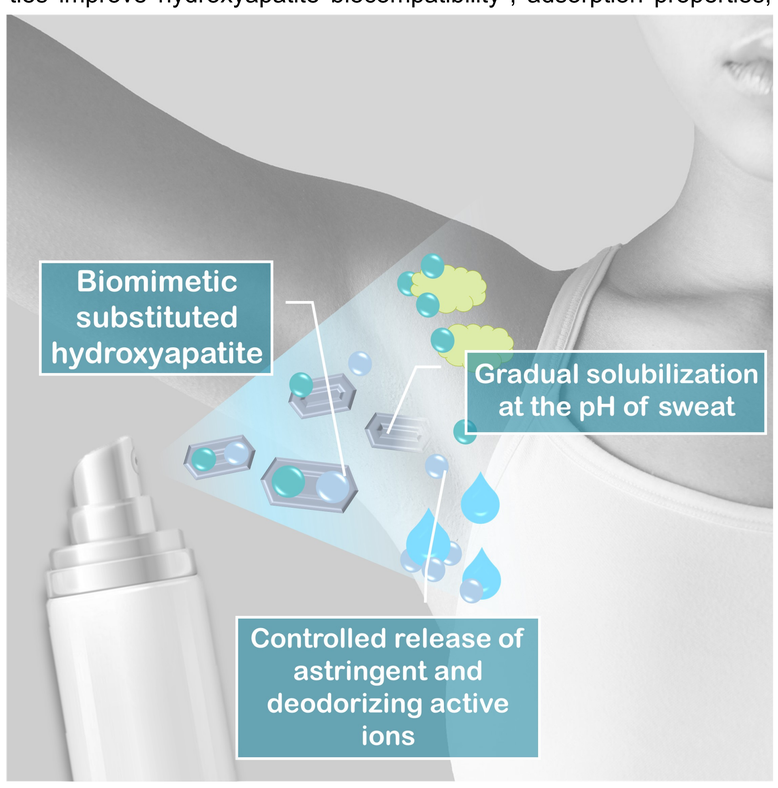

Figure 1. Proposed mechanism of action for substituted hydroxyapatite as antiperspirant/deodorizing ingredient.

Ions of zinc, calcium, aluminum, magnesium carbonate phosphate (substituted hydroxyapatite) is a biomimetic hydroxyapatite functionalized with active ions exerting adsorbent, astringent, deodorizing and bacteriostatic properties that gradually dissolves at the typical pH values of sweat (4-6)[6], thus inducing a modulated release of active ions and producing a long-lasting antiperspirant and deodorizing effect (***Figure 1***).

This gradual and targeted release of ions reduces at the same time their impact. We named this finely regulated delivery system based on biomimetic hydroxyapatite "**Active Phosphate**" (AP) System.

Previously performed *in vivo* test showed the ability of the AP system to act also as an active ingredient to improve skin texture, wellbeing and appearance[7].

Here we demonstrate the efficacy in sweating control of biomimetic ions of zinc, calcium, aluminum, magnesium carbonate phosphate (substituted hydroxyapatite), an innovative high-performing ingredient, which does not release irritating substances on skin, rather improves skin texture and wellbeing and can represent therefore a safer, gentle but effective alternative to traditional antiperspirant ingredients.

MATERIALS & METHODS

Ions of zinc, calcium, aluminum, magnesium carbonate phosphate (substituted hydroxyapatite) was synthetized through a modified wet precipitation method. The antiperspirant activity of a test formulation containing the active ingredient was evaluated with a **gravimetric test** on healthy volunteers[8].

The study was performed on 16 healthy female and male subjects aged between 18 and 65 years. After a clearance period of at least 17 days, during which test subjects were required to abstain from using any antiperspirants and deodorants, half of the test subjects applied an O/W emulsion containing 6% as active matter of the AP under the left armpit and the placebo control O/W emulsion under the right one, leaving the remaining test subjects to be assigned oppositely. Test and placebo formulations were applied once daily for a treatment period of four days. In line with consumer habit, subjects applied 300 mg of each formulation (+/- 10%).

TIME	TEST FORMULATION	PLACEBO
T24h	0.302g	0.528g
T48h	0.501g	0.790g

Table 1. Mean collected perspiration (grams of sweat).

24 and 48 hours after the last daily treatment, test subjects were placed in a controlled environment (temperature 40°C, relative humidity 30-40%) for a 40 minutes warm up period to induce perspiration. At the end of the warm up period, preweighed absorbent pads were placed in both armpits of each test subject, leaving them in the controlled environment for further 20 minutes (collection period); sweat was collected on the absorbent pads, and the pads were weighed again at the end of the collection period. No volunteer withdrew from the study, and no deviation occurred during this study.

The hypothesis that reduction in perspiration exceeds 20% was statistically tested using the **Wilcoxon Signed Rank test**, a non-parametric statistical hypothesis test used instead of Student-t test for populations without normal distribution and N<50.

RESULTS & DISCUSSION

Mean perspiration of test formulation and placebo treated armpits of 16 volunteers, was calculated at 24 and 48 hours after the last daily treatment. Results are summarized in ***Table 1*** and represented in ***Figure 2***.

Mean percent variations in perspiration of the test formulation treated armpits versus placebo treated armpits, at 24 and 48 hours after the last daily treatment are shown in ***Table 2***. 24 hours after the last daily treatment, the mean amount of sweat collected from the test formulation-treated armpits resulted lower by a mean value of 35.47% compared to the mean amount of sweat collected from the placebo-treated armpits.

Statistical analysis has demonstrated the good antiperspirant efficacy of the test formulation at 24 hours according to FDA guidelines, since the reduction in perspiration exceeded 20% in at least 50% of the target population (p≤0.05).

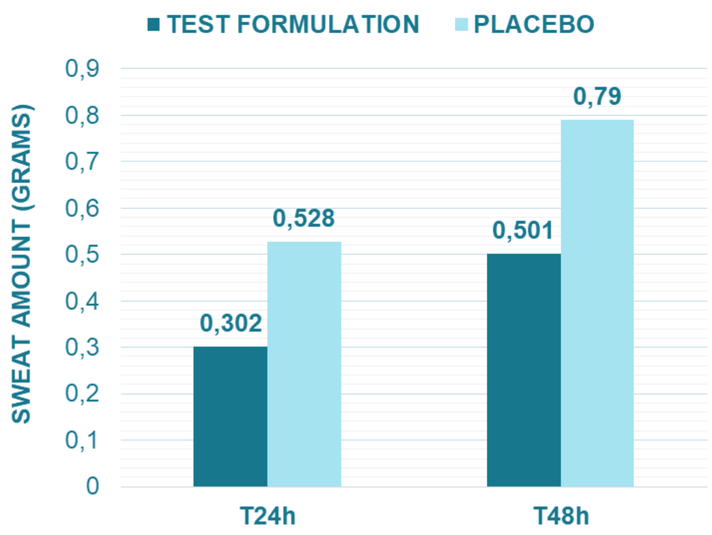

Figure 2. Gravimetric test: Reduction in mean underarm perspiration at 24 and 48 hours after the last application of a formulation containing ions of zinc, calcium, aluminum, magnesium carbonate phosphate (substituted hydroxyapatite) versus a placebo formulation.

48 hours after the last daily treatment, the mean amount of sweat collected from the test formulation-treated armpits resulted lower by a mean value of 30.46% compared to the mean amount of sweat collected from the placebo treated armpits. Statistical analysis has demonstrated the good antiperspirant efficacy of the test formulation at 48 hours according to FDA guidelines, since the reduction in perspiration exceeded 20% in at least 50% of the target population (p≤0.05).

According to the applied experimental conditions, in the subjects submitted to the study, the test formulation containing ions of zinc, calcium, aluminum, magnesium carbonate phosphate (substituted hydroxyapatite) has demonstrated an optimal antiperspirant efficacy, which was statistically significant (p≤0.05), since the reduction in perspiration exceeded 20% in at least 50% of the target population both at 24 and 48 hours after the last daily treatment.

CONCLUSIONS

We here demonstrated, in compliance with FDA guidelines, that ***a test formulation containing ions of zinc, calcium, aluminum, magnesium carbonate phosphate (substituted hydroxyapatite), is able to efficiently decrease underarm perspiration both at 24 and 48 hours and with a single daily application***, in an *in vivo* gravimetric test. The antiperspirant activity of the biomimetic ions multi-substituted hydroxyapatite is significant and comparable to that of traditional antiperspirant based on chloride; however, unlike these, it does not release HCl, other irritating substances or high amounts of metal ions on skin. It can be postulated that the antiperspirant activity of *ions of zinc, calcium, aluminum, magnesium carbonate phosphate (substituted hydroxyapatite)* is exerted through a ***surface mechanism*** synergistically involving both the adsorption properties of substituted hydroxyapatite and the controlled release of active ions, that does not necessarily require the formation of a deeper plug in the sweat duct[9]. Our ingredient may be therefore considered a **safer alternative**, with proven efficacy, to aluminum chloride salts to reduce heavy sweating without producing skin irritation and limiting, at the same time, the impact of the ions, thanks to an elegant, controlled, biomimetic and natural release system. Moreover, ***this ingredient is versatile and can be used in spray, cream, roll-on and stick formulations, claiming a skin-friendly, non-irritant and long-lasting action.***

% OF SWEAT REDUCTION TEST FORMULATION VS PLACEBO	
T24h	-35.47 (p≤0.05)
T48h	-30.46 (p≤0.05)

Table 2. Mean sweating percent reduction of test formulation treated vs placebo treated armpit.

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