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“HAIR COSMETICS AND THERMAL STYLING: FORMALDEHYDE RELEASE AND HUMAN SAFETY ANALYSIS”

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1. Introduction

The growing demand for hair products that promote healthy and beautiful hair has led to a booming market. However, concerns about the safety of certain ingredients, especially formaldehyde, have emerged. Formaldehyde is a colorless, organic compound with a strong, pungent odor, widely used in the chemical industry [1].

Formaldehyde and hydrolyzed keratin were introduced to the hair care market by the Brazilian keratin hair straightening, also known as keratin smoothing or Brazilian keratin treatment (BKT). This technique originated in Rio de Janeiro, Brazil, in 2003, and it has become increasingly popular worldwide among women, regardless of hair type [2]. The keratin products are desirable for women to straighten the hair, reduce the frizz and to increase the shine of the hair shafts, giving the hair a healthy appearance for up to 5 months [2;3].

Unfortunately, formaldehyde has been extensively reported as a toxic, mutagenic, and carcinogenic substance for humans through inhalation and skin contact, causing many eye, throat and respiratory allergies and reproductive problems among hairdressers and costumers, which led to its prohibition as a hair straightener in many countries [3-9]. Although formaldehyde has a well-established toxic potential, its health effects depend on the concentration of this gas in the air, being considered safe if the concentration is lower than 0.2% [3;4;6-8].

Despite the strict regulation of formaldehyde, some hair straightening products contain synonym names in the ingredient list to hide the presence of formaldehyde, contain impurities or some additives that can release formaldehyde (formaldehyde releasers – FR) over the permitted limit when heated or mixed with water [6], such as quaternium-15, DMDM hydantoin, imidazolidinyl urea, diazolidinyl urea, 2-bromo-2-nitropropane-1,3-diol (bronopol), glyoxylic acid, polyethylene glycol, etc. [10;11]. This is particularly concerning because some manufacturers claim their products are formaldehyde-free (FA-free), even though they contain these and other substances [9;11;12]. Additionally, FA can also occasionally be re-formed from auto-oxidation of ethoxylated alcohols in cosmetics [13].

Nowadays, many non-formaldehyde-based keratin-straightening products have been developed, often referred to as Safe Keratin Treatments (SKT). These products primarily contain ingredients such as hydrolyzed keratin, with a combination of glyoxyloyl carbocysteine and

glyoxyloyl keratin amino acids, silicone derivatives, and fatty acids. They work by weakening the hydrogen and salt bonds in the hair, allowing for the interconversion of the cysteine bonds within the hair fibers. This process enables keratin to penetrate deeply into the hair cortex. When the hair is heated, the cysteine bonds are strengthened, effectively locking the keratin amino acids within the hair shaft [2]. However, some of these ingredients can react with each other and release formaldehyde.

Aiming to address the demand for safer alternatives to conventional hair straightening systems, which are often associated with formaldehyde release and its well-established toxicological risks [3;8], a formulation based on glyoxyloyl carbocysteine and glyoxyloyl keratin amino acids was proposed. This system is designed to promote hair alignment and shine while presenting a reduced toxicological potential. The assessment of formaldehyde release was performed to ensure regulatory compliance and to validate the safety of the product during use.

Occupational health guidelines recommend biological monitoring, which detects early biological signs of exposure using biomarkers like peripheral blood lymphocytes and epithelial buccal cells through the cytokinesis-blocked micronucleus (CBMN) assay [14;15] and environmental monitoring, which measures FA concentration levels in the workplace air [14;16]. Methods for detecting formaldehyde in cosmetics are well established and include basic techniques such as colorimetry, which involves the reaction of formaldehyde with chromotropic acid, 2,4-dinitrophenylhydrazine (DNPH), or acetylacetone. More advanced methods include micro-diffusion apparatus with fluorescent illumination, polarography, thin-layer chromatography, high-performance liquid chromatography (HPLC), and mass spectrometry [3].

In this scenario, the challenge for the hair cosmetic industry is to develop formaldehyde-like products that either mimic the effects of formaldehyde or exhibit low formaldehyde release rates, while ensuring safe use. In this study, a hair mask containing a mix of glyoxyloyl carbocysteine and glyoxyloyl keratin amino acids was tested in a clinical trial to assess its safety for customers and hairdressers. Specifically, the objectives of this study were to evaluate the cutaneous, ocular, and respiratory acceptance of a hair mask by observing the absence of adverse events under medical supervision, the subjective perception of the product's fragrance and presence of symptoms through investigative and discomfort questionnaires and to investigate the release of formaldehyde from the product during use and thermal styling, exploring potential sources, health risks, and safety measures.

2. Materials and Methods

This study was conducted in accordance with the principles of the Declaration of Helsinki, applicable regulatory requirements, including CNS Resolution No. 466/12, and in accordance with ICH E6: Good Clinical Practices and Document of the Americas. The protocol was approved by the Independent Ethics Committee of Investiga – Research Institute registered with the National Commission for Research Ethics (CONEP).

Thirty-five (35) healthy female subjects aged 18 to 70 presenting intact skin in the test area, who agreed to the study procedures, were included. The study aimed for about 8 subjects per hair type (dry, oily, mixed, normal) and 12 per hair texture (wavy, curly, coily). Subjects with voluminous hair wanting to reduce volume were also included. No chemical hair treatments were allowed 15 days prior. Exclusion criteria included skin and respiratory diseases, positive irritation responses, pregnancy, breastfeeding, ocular diseases, type 1 diabetes, immunodeficiency, use of corticosteroids, immunosuppressants, and antihistamines. Subjects with reactions to similar products or those unable to avoid other products in the test area were also excluded.

2.1 Investigational Product

The investigational product was a hair alignment mask containing a blend of glyoxyloyl carbocysteine and glyoxyloyl keratin amino acids. Two commercially available support products were used, a shampoo and a thermal protector.

2.2 Clinical Safety Evaluations

At baseline (T0), subjects were evaluated by a dermatologist, an ophthalmologist, and an otorhinolaryngologist in order to confirm the inclusion and exclusion criteria. In the second visit, the eligible subjects underwent the dermatological safety assessments of strand test and patch test (performed behind the ear) using the investigational product to test individual sensitivity to the product (T1). The occurrence of reactions to the product in investigation (investigational product) was assessed 30 minutes (patch test) and 60 minutes (strand test) after the application. If there were signs of reaction or allergy, the subject should be excluded from the study. The approved subjects proceed with the product application. Immediately after the application, new safety assessments were conducted by a dermatologist, an ophthalmologist, and an otorhinolaryngologist (T1-Imm). Finally, subjects returned for follow-up clinical safety evaluations 21 + 2 days post-application (T21).

2.3 Application of Investigational Product

After the initial clinical and safety evaluations, the investigational product and support products were applied by a professional hairdresser. The hair was washed twice with shampoo, dried completely with a hairdryer and carefully detangled with a wide-tooth comb. Using a brush, the application began at the nape (1 cm from the roots) and the product was spread throughout the hair, ensuring thorough absorption, but not applied to the roots. After 60 minutes, the hair was thoroughly rinsed with cold running water, a thermal protector was applied, and the hair was blow-dried straight. The thermal protector was reapplied, and the hair was flat ironed in thin sections ten times with a maximum temperature of 220°C.

2.4 Gas Detection

During the application of the product and hair styling, air samples were collected using sampling pumps with silica gel tubes impregnated with 2,4 Dinitrophenylhydrazine (DNPH), at pre-determined heights and times to assess formaldehyde exposure. Six measurements were performed: four short durations (15 minutes) and two partial periods (morning and afternoon). Samples were analyzed by an independent laboratory, certified in the scope of formaldehyde according to ISO 17.025: 2017 [17].

2.5 Diary and Investigational Questionnaire

Subjects kept daily-logs to record any discomfort after application of the product at the institute and in the following days at home, and an investigative and a discomfort questionnaires (Table 1) to be answered immediately after product application (Timm), and after 21 + 2 days of investigational product application (T21). At the end of the study, the completed daily-logs were collected and any records of feelings of discomfort were evaluated. The discomfort questionnaire was also applied to the hairdressers.

Table 1. Investigative Questionnaire. Adapted from the original.

Investigative Questionnaire (T1-imm)	
Question	Scale
Regarding the intensity of the fragrance at the time of application , would you say it is?	1 – Much weaker than I like 2 – A little weaker than I like 3 – Ideal, just the way I like 4 – A little stronger than I like 5 – Much stronger than I like
Regarding the intensity of the fragrance after application , would you say it is?	
Regarding the intensity of the fragrance at the end of the day , would you say it is?	
Discomfort Questionnaire – Part 1 (T1-imm/ T21)	
Before investigational product application	
Do you have a history of or have you experienced Rhinitis/Bronchitis/Asthma?	3 – Yes, sporadically. 2 – Yes, frequently. 1 – Never had these symptoms.
Do you have a history of or have you experienced shortness of breath?	
Do you have a history of or have you experienced Sneezing/Runny Nose?	
Do you have a history of or have you experienced a sensation of suffocation?	
Do you have a history of or have you experienced Nausea/Queasiness/Nausea/Feeling like vomiting?	
Do you have a history of or have you experienced Headache/Migraine?	
Do you have a history or have you experienced Malaise or Dizziness?	
Do you have a history of or have you experienced ocular discomfort?	
IF YES, describe:	Symptom, Frequency and Intensity.
After investigation of product application	
Did you experience Rhinitis/Bronchitis/Asthma?	2 – Yes 1 – No
Did you experience shortness of breath?	
Did you experience Sneezing/Runny Nose?	
Did you experience a sensation of suffocation?	
Did you experience Nausea/Queasiness/Nausea/Feeling like vomiting?	
Did you experience Headache/Migraine?	
Did you experience Malaise or Dizziness?	
Did you experience ocular discomfort?	
IF YES, describe	Symptom, Frequency and Intensity.

If yes, answer the questionnaire Part 2.

Discomfort Questionnaire - Part 2 (T1-imm/ T21)

What/ Which discomfort(s) did you feel? For each discomfort felt, answer:

 What was the intensity? (1 - Weak, 2 - Medium, 3 - Strong, 4 - Not applicable)

 What was the duration? (1 - A few minutes, 2 - A few hours, 3 - The entire day, 4 - Not applicable)

 How often did it happen? (1 - Once, 2 - Two to three times, 3 - Every time the product was applied, 4 - Not applicable)

 When did it happen? (1 - Immediately after application, 2 - Minutes after product application, 3 - Hours after product application)

2.8 Statistical Analysis

Exploratory analyses were conducted on the collected data according to the specific nature of each analysis. The results of the investigative questionnaire were evaluated using the Z-test for proportions and reported as percentages and frequencies of both negative and positive responses. Similarly, the discomfort questionnaires were reported using percentages and response frequencies. Comparative analyses were conducted at 95% confidence level using XLSTAT 2023 and MINITAB 14 software.

3. Results

3.1 Subjects

Thirty-four female subjects aged 23–69 years (mean: 46 years) completed the study. Self-reported hair types included: 9 dry, 9 oily, 9 mixed, and 8 normal. Self-reported hair textures included: 13 wavy, 12 curly, and 10 coily. All subjects desired to reduce hair volume.

3.2 Safety Assessments

3.2.1 Clinical Safety Evaluation

No subject reported or exhibited objective or subjective clinical signs or symptoms of skin, eye or respiratory discomfort related to the use of the investigational product.

3.2.2 Investigative Questionnaire

The percentage of subjects declaring the fragrance intensity as ideal was significantly higher than those who declared it as “not as strong as it could be or too strong”: during application (76.5% vs. 23.5% weaker/stronger than ideal, $p < 0.001$), after application (73.5% vs. 26.5% weaker/stronger than ideal, $p < 0.001$), and at the end of the day (70.6% vs. 29.4% weaker/stronger than ideal, $p < 0.001$) (Figure 1).

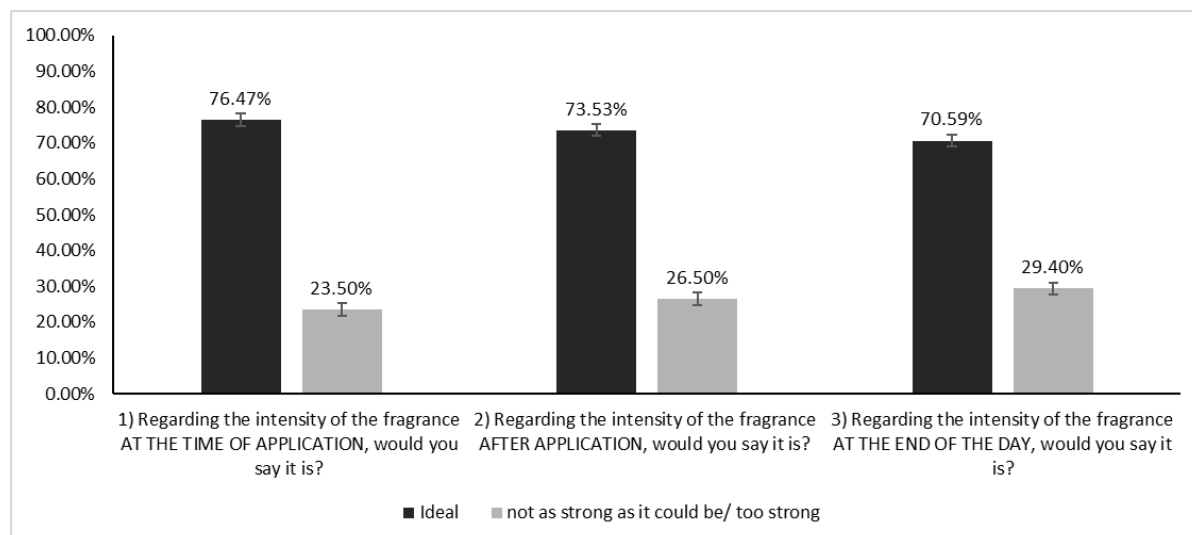


Figure 1. Investigative Questionnaire, subjects evaluated the intensity of the fragrance during application, after application and at the end of the day.

3.3.3 Discomfort Questionnaire

The discomfort questionnaire was administered to both study subjects and hairdressers to assess the presence of symptoms before and after using the product. Before product application, the majority of study subjects (97.1%) reported no history of the evaluated symptoms, except for only 2.9% that experienced rhinitis, bronchitis, or asthma sporadically. After using the product, all study subjects (100%) reported no symptoms of rhinitis, bronchitis, asthma, shortness of breath, sneezing, runny nose, suffocation sensation, nausea, headache, malaise, dizziness, or ocular discomfort. Regarding the hairdressers, 50% reported a history of allergic rhinitis, with medium intensity, but infrequent symptoms before having contact with the product. Other symptoms such as shortness of breath, sneezing, runny nose, suffocation sensation, nausea, headache, malaise, dizziness, and ocular discomfort were reported by a minority of hairdressers. Post-application, no hairdressers (100%) reported any evaluated symptoms.

3.4 Gas Detection

Formaldehyde concentrations were measured using both personal and point sampling methods. Partial-period measurements (ppm) were: Personal samples 1 - 0.05437 ppm (morning); and 2 - 0.06653 ppm (afternoon); point samples 1 - 0.03984 ppm (morning), and 2 - 0.02969 ppm (afternoon). The calculation report of the weighted average for 480 minutes was: 0.03 ppm for partial-period personal samples, and 0.02 ppm for partial-period point samples.

4. Discussion

In this study, no subjective clinical signs of cutaneous, ocular, or respiratory discomfort were reported during application, immediately after, or 21 + 2 days post-application. Neither the study subjects nor the hairdressers reported any symptoms during, immediately after, or three weeks post-application on the discomfort questionnaire at any of these time points. The product's fragrance was also well accepted, with the majority of study subjects finding it ideal before, after, and at the end of the day. These results indicate that the product is safe for use, provided that the application conditions are followed as recommended, and that it was well tolerated by both the study subjects and hairdressers.

Furthermore, formaldehyde concentrations during use and thermal styling were low (0.03 ppm for personal samples, 0.02 ppm for point samples), remaining below the exposure limits established by Brazilian (NR-15) [18] and international regulations (WHO, OSHA, ACGIH) [1;16;19]. Knowing the actual percentage of formaldehyde released is essential, as labeling may not always be accurate. For example, a Brazilian study found all 23 brands tested exceeded the formaldehyde limit, with levels ranging from 3 to 11% [3]. Also, an Egyptian study indicated hairstylists are exposed to formaldehyde above standard limits during hair straightening [20], with a positive correlation to the duration of exposure.

The main ingredients of the product evaluated in this study were Glyoxyloyl Carbocysteine and Glyoxyloyl Keratin Amino Acids. These ingredients are effective in smoothing and aligning hair, while also providing strength, moisture, and volume. Although there are limited studies reporting safety concerns related to glyoxyloyl carbocysteine, such as causing severe acute kidney injury (AKI) in a 13-year-old girl [21] and severe vomiting and scalp inflammation in a 10-year-old and 17-year-old girls [22]. However, these reports lacked specific information regarding product concentration and exposure duration. Even so, such cases underscore the potential nephrotoxicity of such products and underscore the need for accurate labeling and regulation to prevent health risks. It is important to note that all reported cases involved very young patients, which could be associated with a more severe reaction, a demographic for which these products are neither intended nor approved in many countries.

In Brazil, active ingredients like "Cysteamine HCL", "Glyoxylic Acid", "Glyoxyloyl Hydrolyzed Wheat Protein/Sericin" and the combination of "Glyoxyloyl Carbocysteine + Glyoxyloyl Keratin Amino Acids," are registered but not yet included in the "List of permitted active ingredients in cosmetic products for straightening or curling hair." These ingredients are currently under re-evaluation based on RDC No. 409, of 2020 [23].

Celik, Korkmaz, and Dogramaci (2021) [24] investigated the adverse effects of Brazilian keratin treatments on the skin, finding that these treatments can induce allergic contact dermatitis and significant facial edema, likely due to formaldehyde or formaldehyde-releasing agents. This underscores the need for increased awareness and caution among consumers and professionals. Therefore, the absence of adverse reactions, including dermatological, ophthalmological, and respiratory discomfort, and the low formaldehyde release observed for the hair mask in this study are considered very positive outcomes. However, a long-term study to evaluate the cumulative exposure of hairdressers to formaldehyde gas is important. Long-term exposure to volatile organic compounds (VOCs), including aldehydes, has been associated with symptoms such as a runny nose, headache, eczema, nasal congestion, cough, and discomfort with strong odors. These symptoms were prevalent among Swedish hairdressers, particularly those with over 20 years of experience, highlighting the need for exposure control measures in hair salons [25].

Our findings align with the safety levels of formaldehyde in hair products when used correctly. The safety of hair products is a growing concern. This study contributes to the understanding of the risks associated with formaldehyde and formaldehyde releasers and reinforces the need for stringent regulations and safe application practices. Implementing environmental and biological monitoring measures can help protect the health of beauty professionals and consumers. It is also important to highlight that uninformed stylists may not be adequately protecting themselves or their clients from formaldehyde exposure. Customers should always ask about the products being used and carefully read label information, as it may not always be accurate. Thorough studies on ingredients are essential to ensure the safety of these products and their effects on different hair types.

This study will not only contribute to a broader understanding of the risks associated with formaldehyde exposure in beauty salons but will also provide a foundation for the development of mitigation strategies and safety recommendations to protect the health of workers and clients, ensuring a safer and healthier working environment for all parties involved.

Regarding the study's limitations, although it was conducted with a diverse group of subjects and under controlled conditions, some limitations should be acknowledged. The relatively small sample size and limited study duration may not have captured all possible long-term effects. Future studies with larger samples and extended follow-up periods will be necessary to confirm these findings.

5. Conclusion

The results of this study indicate that, when used according to guidelines, the evaluated hair products are safe and do not present significant risks of formaldehyde release above regulatory limits. However, continuous vigilance and education of beauty professionals about safe practices are essential to ensure the health and safety of all involved.

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