Chapter

Cosmetovigilance in Hair Straighteners: Determination of Formaldehyde Content by Spectrophotometry and Label Evaluation

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Abstract

The aim of this work was to identify and quantify formaldehyde present in commercial hair straightening formulations, the application of cosmetovigilance from organoleptic/physicochemical tests and label analysis being approached. Samples A1, A3, A5, and A8 had a formaldehyde concentration ranging from 1.5 to 3.83% (w/v), corresponding to concentrations of 7.5, 16.45, 7.9, and 19.15 times higher than that allowed by the National Agency of Sanitary Monitoring (ANVISA), resulting in strong odor characteristic of this active substance. Of these samples, A3 and A5 did not indicate the presence of formaldehyde on the label besides ignoring the warning information and restrictions of use. The absence of the registration number granted by ANVISA for sample A5, which may be an indication of a clandestine product, was also verified. As to the organoleptic and physicochemical properties, only the A2 sample presented different viscosity and centrifugation results. In view of these results, it was concluded that 50% of the analyzed products were reproved because of the presence of formaldehyde out of the allowed concentration, being evident the importance of the implantation of cosmetovigilance system to guarantee the final quality of the cosmetic products, mainly in view of the safety and efficacy of these products.

Keywords: hair straightening, formaldehyde, mandatory labeling

1. Introduction

The beauty market, including toiletries, perfumes, and cosmetics, is one of the fastest growing of all market segments. According to data collected by the Brazilian Association of Personal Hygiene, Perfumes and Cosmetics Industry, Brazil is the third largest sales market with a turnover of approximately R $ 29.4
billion in 2011 and the world leader in hair straighteners and conditioners, with 37.3 and 18.8% of the market, respectively [1]. Hair is increasingly exhibited as a form of expression and affirmation of the personality, and therefore, the cosmetics market presents a range of products with the resources to treat and embellish them [2]. The progressive brush is a hair straightening procedure, introduced in the Brazilian beauty salons in recent years, which contains formaldehyde in its composition and promises a lasting smoothing, around 1–4 months, becoming a fever in beauty salons [3].

According to the National Agency of Sanitary Monitoring (ANVISA), the incorporation of formaldehyde into the hair straightener is prohibited, as it can cause serious damages to the user of the product and to the professional that applies it, such as irritation, pain, and burn in the skin, injuries in the airways, and irreversible damage to the eyes and hair [4]. Health legislation permits the use of formaldehyde in cosmetic hair products only as a preservative in a maximum concentration of 0.2% and as a nail hardener at a concentration of up to 5%, in accordance with Resolution 15 of 2013 [5].

In order to guarantee the safety and efficacy of cosmetic products, the cosmetovigilance system was created and implemented in Brazil, through Resolution RDC No. 332, dated December 1, 2005 [6]. This resolution was elaborated from the MERCOSUR resolution to the member countries to implement this system, being delegated to the competent national bodies of each associated country [7].

Cosmetovigilance has the function of monitoring the response that the product will cause in the market, analyzing the adverse events caused by cosmetics, identifying the risk involved in the use of these products, and taking pertinent behaviors according to the established cause relationship [8, 9].

Despite the risks and prohibitions, there is a variety of products sold to beauty salons that contain formaldehyde in its composition. These products are used for the hair straightening process, and there seems to be an ignorance of the legislation by hairdressers, providing the indiscriminate use of this substance for this purpose [10]. Therefore, the chapter proposes to identify and measure formaldehyde in commercial formulations of permanent hair straighteners and progressive, as well as evaluating the organoleptic and physicochemical properties and correlate results from the information provided by manufacturers on the labeling of the products, in accordance with the annexes IV and V of DRC 211/2005.

2. Material and methods

2.1 Reagents

For the accomplishment of this research, the following reagents were used: formaldehyde PA 37% (Impex), 99% chromotropic acid (disodium dihydrate salt, Sigma-Aldrich), and 98% magnesium sulfate (Sigma-Aldrich), all of analytical grade. Distilled water was used for the preparation of all solutions.

2.2 Equipment used in the experiment

Spectrum spectrophotometer SP 1102; Nova thermostatic shower, model NI 1254; pH meter Hanna, model pH 21; analog rotational viscometer MDJ-1; Centribio centrifuge, model 80-2B; and analytical balance Edutec model FA-2104 N.
2.3 Methods

2.3.1 Collection of samples

For the development of the research, eight samples of permanent and progressive hair straighteners in cosmetic cream from different manufacturers were collected in salons of the municipality of Cuité, PB. The samples were named A1–A8, and their qualitative compositions are described in Tables 1 and 2.

2.3.2 Dosing of formaldehyde

The methodology used to identify and quantify the formaldehyde content in progressive brush products was applied according to the standard method.

| SAMPLES | QUALITATIVE COMPOSITION |
|---------|--------------------------|
| A1      | Laurilet; Citric acid; Hydroxyestearyl; Berrenyl cetyl; Cetyl alcohol; Frangrance and Aqua (water); Theobroma Cacao; Collagen; EDTA; BHT; Cetitrimethylammonium chloride; Lanolin; Tocopheryl acetate; Magnesium acetate; Formaldehyde; Phenoxyethanol and Isobutyl Paraben. |
| A2      | Aqua, Parfum (amyl cinnamal, anise alcohol, benzyl alcohol, benzyl benzoate, butyphenyl methypropional, citral, citronellol, coumarin, eugenol, geraniol, hexyl cinnamal, limonene, linalool); Cetearyl alcohol; cyclomethicone; Sodium PCA; Cera Alba; Isononyl Isononanoate; Behentrimonium methosulfate; Isosorbide Decaprylate; Aspartic Acid; Arginine; Proline; Tryptophan; Glutamic Acid; Cysteic Acid; Glycine; Leucine; Serine; Butylene Glycol; Cetrimonium Chloride; Argania Spinosa Kernel Oil; Cocos Nucifera Oil; Gardenia Tahitensis Flower; Tocopherol; Euterpe Oleracea Fruit Extract, Bixa Orellana Seed Extract; Paulinia Cupana Fruit Extract; Shea Butter Cetyl Esters; PEG 90M; Glyoxylic Acid; Carbocysteine; Oxalic Acid; Acetamide MEA; (Methylisothiazolinone, Phenethyl Alcohol; PPG-12 Methyl Ether); Cinnamomum Zeylanicum Bark Extract; Corus Calamus Root Extract; Commophora Myrrha Resin Extract; Olea Europae (olive) Fruit Oil; Citric Acid; Malic Acid; Tartaric Acid; Erythorbic Acid; Gallic Acid; Boric Acid; Sorbic Acid; Oxoacetamide Carbocysteine and Oxocacatetamide Amino Acids, Acetic Acid; Benzoic Acid. |
| A3      | Aqua; Cetearyl Alcohol; Cetil Alcohol; Ceteareth-20, Glyceryl Stearate; Behentrimonium Methosulfate/Cetearyl Alcohol, Cetrimonium Chloride; Quaternium-70; Cyclomethicone; Propylene Glycol; Poliquaternium-55; Creatine; Hydrolyzed Keratin; Methyparaben; Propylparaben; Disodium EDTA; Citric Acid; Parfum. |
| A4      | Polyquaternium-67; Aqua (Water); Peg-14m; Butyrospermum Parkii (Shea Butter); Behentrimonium Methosulfate; Cetearyl Alcohol; Behentrimonium Chloride; Isopropyl Mirystate; Glyoxyloyl Carbocysteine and Glyoxyloyl Keratin Amino Acids; Aminopropyl Phenyl trimethicone; Methylchloroisothiazolinone; Methylisothiazolinone; Parfum (Fragrance). |

Table 1.
Qualitative compositions described on the labels of the capillary straighteners (A1–A4).
2.3.3 Preparation of solutions

The stock solution of formaldehyde with of 1000 mg. L\(^{-1}\) was prepared using 2.7 ml of 37% (v/v) formaldehyde solution diluted with distilled water in a 1000 ml volumetric flask. An aqueous solution of chromotropic acid (CA) 5% (w/v) was prepared, dissolving 1.25 g of solute with distilled water in a 25 ml volumetric flask. An aqueous solution of magnesium (MgSO\(_4\)·7H\(_2\)O) 60% (w/v) was prepared, dissolving 60 g of solute with distilled water in a volumetric flask 100 ml.

2.3.4 Analytical curve for the identification of formaldehyde

The identification of formaldehyde in the solutions was done through the reaction that occurs between the chromotropic acid and formaldehyde in the presence of magnesium after heating, thus producing a colored compound, indicating the presence of formaldehyde in a solution. For the determination of the analytical curve of formaldehyde, the following test was performed: 90, 120, 150, 180, 210, 220, and 230 μl of stock solution containing formaldehyde were transferred to test tubes. Then, 290 μl of solution of 5% (w/v) chromotropic acid and 3.0 ml of solution of 60% (w/v) magnesium sulfate, with stirring. The tubes were heated for 60 minutes in a steam (100°C), followed by cooling to 25°C. The solutions were transferred to 25 ml flasks and the volume filled with distilled water, obtaining the concentrations of formaldehyde (ppm): 3.6, 4.8, 6.0, 7.2, 8.4, 8.8, and 9.2, respectively. The measurements of absorbance were recorded at 535 nm. All reviews were carried out in triplicate, in order to guarantee the accuracy of the results obtained.

Table 2. Qualitative compositions described on the labels of the capillary straighteners (A5–A8).

| SAMPLES | QUALITATIVE COMPOSITION |
|---------|-------------------------|
| A5      | Água Hidrolizada Keratin PG-40; Hidrogenated Castor oil; Cetrimonim Chloride; Pantenol; Laureth-23; Glicerina; Propilene Glicol; Hidrolizado Wheatprotein; Poliquaternium-10; Hidroxietilcellulose PG-40; Whale spermaceti with essence (active principle). |
| A6      | Aqua/Water; Propylene Glycol; Cetearyl Alcohol; Ceteareth-20; Etdronic Acid and Phosphoric Acid; Ethanolamine; Thioglycolic Acid; Honey Extract and Propolis Extract and Pollen Extract and Royal Jelly Extract; Sodium Laureth Sulfate; Parfum/Fragrance. |
| A7      | Aqua, Paraffinum Liquidum, Ammonium Hydroxide, Thioglycolic Acid, Cetearyl Alcohol, Avena Sativa, Petrolatum, Propylene Glycol, Polyquaternium-7, Lanolin, Cetethareth-20, Parfum, Etdronic Acid, Amodimethicone (and) Tallowtrimonium Chlroride (and) Nonoyanol-10. |
| A8      | Aqua; Cetearyl Alcohol; Cetil Alcohol; Petrolatum; Paraffinum Liquidum (Mineral Oil); Butyrosperum Parkii Butter; BHT; Cetyl Lactate; Chenopodium Quinoa Extract; Polyquaternium-10; Cetrimonium Chloride; Citric acid; Hidrolyzed Keratin; EDTA; Dimethicone; Laureth-4; Laureth-23; Formaldehyde; Methylchloroisothiazolinone; Methylisothiazolinone; Parfum; Hexyl Cinnamal; Alphaisomethyl Ionone; Linalol; Coumarin. |

recommended by the National Institute of Occupational Safety and Health [11], followed by the modifications described by Gasparini et al. [12].
2.3.5 Determination of formaldehyde in the sample

For each commercial sample, 3.0 g was weighed and then dissolved in about 20 ml of distilled water, and the final volume was completed to 100 ml, yielding a solution with concentration (C1) of 30,000 μg ml⁻¹. After 5.0 ml of this solution (C1) were diluted in 25 ml of distilled water (C2 = 6000 μg ml⁻¹). Aliquots of 1.0 ml of the solutions (C2) were transferred to test tubes together with 290 μl of chromotropic acid 5% (w/v) and 3.00 ml of magnesium sulfate 60% (w/v). The tubes were heated for 60 minutes in a steam bath (100°C), followed by cooling to 25°C. The solutions were transferred to 25 ml volumetric flasks, and then the volume was filled with distilled water resulting in a concentration (C3) of 240 μg ml⁻¹. The measurements of absorbance were performed at 535 nm.

2.3.6 Organoleptic and physicochemical properties

The organoleptic and physicochemical tests were performed to assess the characteristics of the products in study. The organoleptic and physicochemical characteristics evaluated were odor, color, appearance, pH, viscosity, density, and centrifugation [13], which were correlated between samples.

2.3.7 Determination of pH

For the determination of the pH, the potentiometric method was used. The samples were diluted to 10% (w/v) in distilled water, at room temperature, in triplicate [13–15].

2.3.8 Determination of viscosity

The viscosity was measured in triplicate in an analog rotary viscometer using 40 g of sample, spindle 4 and speed of 6 rpm. Next, the rotor was inserted vertically into the sample free of blister up to the groove of the rotor rod, and the apparatus was leveled, by reading the viscosity according to the operating procedure of the device [13].

2.3.9 Determination of density

The density was determined by pycnometry. Initially the empty pycnometer (M0) was weighed, first, with distilled water (M1) and, finally, (clean and dry) with the sample (M2). The masses were noted for calculation using the following formula [13]:

\[
d = \frac{M_2 - M_0}{M_1 - M_0}
\]

where d is the sample density in g/cm³; M0 is the mass of the empty pycnometer, in grams; M1 is the mass of the pycnometer with distilled water, in grams; and M2 is the mass of the pycnometer with the sample, in grams.

2.3.10 Centrifuge test

From each sample, 5 g was placed in centrifugal tubes and submitted to cycles of 1000 and 2500 rpm for 15 minutes each. The homogeneity of the study formulations was evaluated by observing macroscopic separation of phases after performing the described procedure [13, 14, 16].
2.3.11 Label analysis

A qualitative analysis of the primary and secondary packaging of the tested products by a critical visual investigation was carried out, following the criteria laid down by national legislation—RDC 211/2005 which defines the labeling rules for cosmetic products [17] and RDC 332/2005 which deals with regulation and implementation of cosmetology in the cosmetic industries [6]. The analyzed items were specified according to Figure 1.

Figure 1.
Mandatory items on labeling of capillaries straighteners according to Annexes IV and V of DRC 211/2005.

3. Results

3.1 Analytical curve for the identification and determination of formaldehyde

The identification of formaldehyde was evidenced by the production of a pink compound resulting from the reaction between chromotropic acid and formaldehyde in the presence of magnesium sulfate. The analytical curve data, resulting from the average of three calibration curves, were adjusted by linear regression (Figure 2), whose equation of the line is given by absorbance = 0.0922 × [formaldehyde solution, chromotropic acid, and magnesium sulfate] (ppm) − 0.0234. The correlation coefficient obtained was 0.996, a significant linear regression. Samples A1, A3, A5, and A8 developed a coloration after heating, indicating the presence
of formaldehyde in these formulations, which tends to be as darker as greater the concentration of said substance. The samples A3 and A8, on the other hand, presented more intense in relation to others, which justifies a higher concentration of formaldehyde. The percentages of formaldehyde calculated by the equation from the analytical curve confirm these results and are described in Table 3.

### 3.2 Organoleptic and physicochemical characteristics

The results obtained in organoleptic and physicochemical tests of the study samples are listed in Table 4. Regarding appearance and color, observed macroscopically, the samples presented as homogeneous creams, whether or not colored and without precipitation or exudation. The odor was checked directly through the smell, being possible to smell characteristic of formaldehyde in samples A1, A3, A5, and A8, capable of causing some mucosal irritation and burning in the eyes during observation, confirming symptoms caused by exposure to formaldehyde. The sample A5, although with a strong chocolate odor, failed to mask the presence of formaldehyde in the product. Samples A6 and A7 showed an odor of sulfur, a characteristic of thioglycolic acid. The samples A2 and A4 presented no strong or unpleasant smell, only the essence odor used in these products.

 Samples A2 and A4 showed a pH of very acid (1.0 and 1.3, respectively), which may damage the capillary wires [18]. In the other hand, the sample A8 has a pH
within the range that tends to assist in the maintenance of wires. The samples A1, A3, and A5 also have a pH slightly acidic, being able to close the capillary cuticle and help in preserving the color deposited in the hair. The samples A6 and A7 presented extremely high pH, a characteristic of products for permanent straightening.

The analyzed samples did not present significant variation in relation to the determination of the density and did not need to correct the weighing to carry out the dosing of the formaldehyde.

The formulations showed without phase separation, precipitation, formation of caking, and coalescence, except the A2 sample that presented phase separation after being subjected to the centrifugation.

The viscosity results can be in Figure 3. These results point to discrepant values between formulations, ranging from extremely low (A2) to extremely high (A6 and A7).

### 3.3 Label analysis

The results of the analysis of the product labels are presented in Table 5. Samples A1, A3, A5, and A8 presented formaldehyde content in the procedure
spectrophotometric assay; however, only samples A1 and A8 indicated formaldehyde in their composition. Samples A3 and A5, in addition to the absence of the substance, presented other irregularities on the label, both ignoring the warning information and usage restrictions. Sample A5 does not yet have registration number granted by ANVISA, evidencing the likely clandestine origin of this product.

The samples A2, A4, A6, and A7, whose labels said formaldehyde-free, are not really content of the substance, being in compliance and complying with the technical requirement legislations.

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Table 5.
Analysis of the labels of the products under study according to Annexes IV and V to DRC 211/2005.
4. Discussion

According to the NIOSH 3500 [11] reference method, formaldehyde is determined by spectrophotometry through reaction with chromotropic acid in the presence of concentrated sulfuric acid, after heating, to obtain a soluble polymer violet-red that can be detected in length of wavelength of 580 nm. However, although the method is selective, not suffering interference from other aldehydes, it has some drawbacks. The main one is the use of concentrated sulfuric acid by the toxicity and corrosivity that it presents. Therefore, some authors have proposed modification methodology that could minimize these disadvantages [12, 19–23].

According to Toutianoush et al. [22], it is possible to dose the formaldehyde by spectrophotometry in the presence of a solution of magnesium sulfate (MgSO₄•7H₂O) instead of sulfuric acid. A red/pink is produced after heating of formaldehyde with an excess of chromotropic acid in a steam bath. In the absence of magnesium sulfate, this reaction does not occur. It is likely that the oxygen atoms of the cyclotetrachromotropylene-hydroxyl are pre-arranged for complexation with magnesium. Gasparini et al. [12] used this method to dose formaldehyde disinfectants and hair care products, considering the adequate method, low operating cost, and simplicity and selectivity, meeting the requirements of green analytical chemistry.

Thus, the applicability of the proposed method to determination of formaldehyde in straightening hair products of different brands proved to be appropriate, possible to identify the presence of formaldehyde in samples A1, A3, A5, and A8 in concentrations ranging from between 1.5 and 3.83% (w/v), i.e., concentrations 7.5; 16.45; 7.9 and 19.15 times that allowed by ANVISA [5].

Some authors also dosed formaldehyde in commercial formulations of hair straighteners using methods such as HPLC, gas chromatography, and mass spectrometry, finding concentrations of 1.6–11.5%, similar results to that of this research, with concentrations above that accepted, evidencing the use of formaldehyde as a hair straightener and not just as a preservative at the maximum concentration of 0.2%, as recommended by health legislation. This shows the lack of supervision by regulatory institutions and the deep lack of knowledge or lack of concern for part of consumers and professional hairdressers in face of the risks that these products bring to health [24, 25].

In addition to the assay, it is also important to analyze the organoleptic and physicochemical characteristics of a cosmetic formulation, because usually the texture, odor, color, and appearance of the product are examined before your purchase; these being important parameters from the commercial point of view, consumers may or may not be attracted to these characteristics. The sample A5 presents a dark-brown tone and chocolate essence; these characteristics tend to seduce the consumer. The color of a product, however, has no connection with the presence or absence of formaldehyde, differently from the intense odor, which may be indicative, since even using extremely high essences fragrant, it is still possible to smell it.

The pH of the hair strands ranges from 4.5 to 5.5. Capillary formulations with extreme pH variations can damage the capillary wire, because the hair shrinks and stiffens or even dissolves completely at very high pH acid or increases porosity as the layers of cuticle dilate, resulting in a dry appearance, opaque, reaching to complete hair dissolution in strongly alkaline pH. The pH values of samples A1, A3, A5, and A8 were compatible with the hair samples, while samples A2, A4, A6, and A7 had a pH out of the tolerated range, the integrity of the capillary wire [18]. In this way, products for professional use should be used with caution and applied by trained professionals.
Viscosity is a measure of resistance of a flow system when submitted to a mechanical stress. Therefore, the higher the viscosity, the higher the resistance and the force to be applied to flow with a certain velocity [26]. In the case of the products tested, there was a considerable variation of this parameter, of samples having viscosities less than 4000 cP to samples with viscosities above of 12,000 cP, thus presenting flow profile applicability. The viscosity results can also inform the influence of the sedimentation rate of the droplets present in the cosmetic cream form, complementing the result of the centrifugation.

The centrifugation test provides quick information about phase separation, thus predicting whether the product will separate as a function of time [13], which can lead to significant differences in the content of assets. In the present study, only the A2 sample presented separation of post-centrifugation phases, which can be influenced by the low viscosity of the sample (566 ± 57.7 cP). According to Stokes’s law, the speed of sedimentation is inversely proportional to viscosity and directly proportional to the size of the droplets, the gravity, and the density difference between the dispersed medium and dispersant [27].

The evaluation of product quality parameters for progressive brush becomes essential, once beauty salons are frequently visited by sales promoters that offer products that are capable of providing a “true miracle” in straightening the hair without formaldehyde in its composition. However, they may have a high concentration, masked by an extremely fragrant and unidentified formula of its presence on the label [28], which could be proven in the present study, where 50% of the products for hair straightening analyzed were disapproved due to the presence of formaldehyde out of the concentration allowed, as well as irregularities in the labels.

5. Conclusion

The chapter is important to the cosmetovigilance system to ensure the final quality of cosmetic products, taking into safety, efficacy, and information to ANVISA, to the manufacturer, and to the consumer. In this way, this system may provide numerous benefits to the cosmetics industry as a whole. As measures, it would be important to distribute orientation books and flyers of cosmetic products since the vigilance is not only the responsibility of companies but also of the consumers and competent institutions.

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