

Quality control of cosmetics: case of baby wipes sold in Yaounde

Abstract

Cosmetic products have increasingly bad reputation because the risks associated to their uses unleashed passions and controversy; special attention is therefore required in the use especially those intended for children under 03 years, given the specific anatomical and physiological fragility of their skin. Among cosmetics for children, wipes are included in the search results because their use is convenient and does not require water. They are sold all over the world, specially designed to clean the baby's seat area. Our study consisted to determine the technico-regulatory, physicochemical and microbiological quality these baby wipes sold in the city of Yaounde. 07 groups of samples representing 07 brands of baby wipes most sold in Yaounde were analyzed according to the European Cosmetic Regulation EC No. 1223/2009 and the General Standard for cosmetics in Cameroon (NC 801: 2013). In addition, an inventory of the wipes frequency of use in Yaounde has been done, to guide us on the choice of brands to analyze. *We founded as results that the non-conformity rate was 100% for the label control, 71.43% for physicochemical tests (with phenoxyethanol detected in 43% of samples tested and MIT in 28.57% of samples tested) and also 28.57% non-conformity rate for microbiological testing.* At the end, an evaluation of these results has permit identified some causes of non-conformities such as non-compliance with standards rules, poor storage conditions in the retail outlets and the absence of a cosmetic regulations to Cameroon. To overcome these problems, recommendations were made intended to all stakeholders, including organizing awareness campaigns on babies cosmetic product safety and the importance of reading labels of cosmetics, establish a national strategy for systematic control of cosmetics quality and a redraw from the market all wipes containing prohibited ingredients such as Methylisothiazolinone, phenoxyethanol.

Keywords: quality control, cosmetics, cosmetic ingredients, safety

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Introduction

According to the Cosmetics Regulation (EC) No 1223/2009, a cosmetic is "any substance or preparation intended to be placed in contact with the various external parts of the body including the skin, hair and capillary systems, nails, lips and external genital organs or with the teeth and the oral mucosa, with an aim exclusively or mainly to cleaning them, perfuming them, changing their appearance, protect, maintain in good condition or correcting body odors." This regulation does not foresee any authorization for the placing on the market of cosmetic products, but requires those responsible for placing on the market to ensure the safety of these products. Each cosmetic product is considered to be the result of a combination of ingredients.¹ Therefore, the regulation (EC) No 1223/2009 imposes an assessment of ingredients including: the absence of prohibited substances, the restrictions, compliance labeling, good microbiological quality and conformity of physicochemical analysis (pH, allergens, preservatives), especially for products intended to children under 03 years. According to the European classification of cosmetics, baby wipes belong to first-class cosmetic products and are non-rinsed.² These products are generally composed of a non-woven substrate made of synthetic fibers and/or cellulose, impregnated with a cleaning substance which some manufacturers say it contains parabens, phenoxyethanol, isothiazolinones, etc.³ This complex composition is likely to present risks to public health in contact with the delicate skin of young children. This study to evaluate the microbiological quality of outstanding wipes in Yaounde and their physicochemical composition in order to communicate the risks associated with use of these cosmetic.

Materials and methods

Materials used for data collection

A preliminary investigation concerning the use of baby wipes was conducted in Yaounde over a period of 21 days with a guide sheet consists of 13 questions. The survey covered 450 individuals considered as key item regarding the health of children, including 400 women from all social classes and 50 health professionals.

Control of labeling

The conformity assessment of the information mentioned on the label wipes marketed was done according to the requirements of the Cameroon CN standard 804: 2013, published by the Agency for Standards and Quality (ANOR).

pH measurement

The pH measurement was performed using qualify and calibrated pH meter. For each sample tested, 03 reading pH values were taken to determine the mean. For this test, we relied on the recommendations of the National Agency of Medicines Safety and Health products (ANSM) in 2012 about the safety of products intended for children under 03 years.⁴ Thus, a wipe will be considered safe for the child's health if it has a pH value between 4.5 and 6.

Highlighting alcohols present

Highlighting alcohols present was made by a color test with potassium dichromate, a method referenced in the collection.⁵ For this analysis, we extracted genty in a beaker of 10ml, 5ml of the

wipes moisturizing lotion and 2ml of the initially prepared solution of potassium dichromate was added to observe the change of color.

Search of cosmetic prohibited ingredients in wipes

Phenoxyethanol or 2-phenoxyethanol:

A preliminary extraction was made in distilled water at 37°C and the identification was done by UV-visible spectrophotometry (according to European Pharmacopoeia⁶) with a reading spectral region from 240 to 350nm. Phenoxyethanol absorption spectrum shows two peaks with absorption maximum wavelength at 269nm and 275nm.

The Methylisothiazolinone (MIT) or 2-Methyl-4-isothiazolin-3-one:

A preliminary extraction was made in ethanol 95°C and the resulting mixture placed in an ultrasound bath for 30 min at 25°C. The identification was done by UV-visible spectrophotometry using a method described,⁷ with the reading of a single spectrum maximum absorption at 275nm. The calculation of concentrations was made following Beer Lambert law and calculation of the MIT safety margin was based on its systemic exposure and toxicological parameters. According to the guidelines of the SCCS (Scientific Committee on Consumer Safety) in 2012,⁸ these safety margin calculations are performed using the following formula.

Microbiological analysis

The volume taken for analysis was 5ml for each trial (5 trials per sample) and diluted to one-tenth (1/10). We focused our samples by vacuum filtration. To evaluate the microbiological conformity, three tests were carried out in particular, a total yeasts and molds count on TSA agar (ISO/TS 11133-2/A1) incubated at 30°C for 5 days (and validation of enumeration on SDA: Sabouraud dextrose agar for *Candida albicans*); enumeration and validation of total mesophilic aerobic organisms on PCA agar (ISO 4833) incubated at 37°C for 72 h (in search of *Staphylococcus aureus* and *Pseudomonas aeruginosa*), finally a specific search for *Pseudomonas aeruginosa* on Mueller Hinton agar incubate the medium at 37°C for 48h. Given the origin of different brands of wipes, analysis of our results was done according to the European Cosmetic Regulation EC N° 1223/2009 and to the General Standard for cosmetics in Cameroon (NC 801: 2013).⁹

Results

Results from survey forms

Brands of baby wipes used in yaounde: 400 women were interviewed concerning the use baby wipes: 338 women (84.5%) used wipes for hygiene of their children and 67 women (15.5%) do not use wipes for their children; What has therefore helped to identify 20 brands of baby wipes used in Yaounde but only 07 brands have retained our attention due to their high percentages in terms of use.

Public awareness level on the risk of babies wipes toxicity: Table 1 showed that majority of the tested population (84.89%) was not aware of the risk of baby wipes toxicity, including some health professionals.

Distribution of samples for analysis: Table 2

Labeling control

One hundred percent (100%) of the brands controlled was in non-conformity regarding the labeling. The main discrepancies were: the

absence of mandatory particulars, misuse of language, lack of batch number and an incomplete list of ingredients.

Table 1 Public awareness levels on the risk of babies wipes toxicity

Sensitization	Workforce	Percentage
Mother	YES	36
	NO	364
Health professional	YES	32
	NO	18
Total		450
		100%

YES, people already aware of the toxicity of baby wipes.

NO, people not aware of the toxicity of baby wipes.

Physico-chemical analysis

pH measurement: Figure 1 shows that

- The pH values are different depending on the samples, but all oscillate in the range of the recommended pH for children, with the exception of E6 and E7 coming out of the standard;
- The measured pH does not match the pH indicated on the labels. Amount the 07 samples tested, 02 were indications of the pH (5.5), it is revealed during the testing of different pH values of that found on the labels.

Highlighting of alcohols presence in wipes: This test revealed the presence of alcohol in 28.57% of samples.



Photo 1 Colorful test with Potassium dichromate

Identification of Phenoxyethanol: For the 07 samples tested, 03 (42.86%) showed positive results with each presenting two peaks with maximum absorption around 269 nm and 275 nm; these include E1, E2, and E7. The other 04 samples (57.14%) had peaks which were however not specific to those of phenoxyethanol (Figure 2).

Identification and dosage of Methylisothiazolinone (MIT)

UV spectra revealed that amount the 07 samples tested, 02 (28.57%) had a maximum absorption peak around 275nm specific to MIT, with different absorbance (Figure 3).

Table 2 Samples of wipes collected for analysis

Brands	Baby Wipes	Moby Baby	Fresh Runy	Baby Sita	Oridel	Corine De Farne	Tiof
Quantity	3	3	3	3	3	3	3
Collection site	Ngoa-Ekele perfumery	Santa Lucia Mokolo	DOVV Mokolo	Central Market perfumery	Omnisport perfumery	Casino supermarket	Nkolbisson perfumery

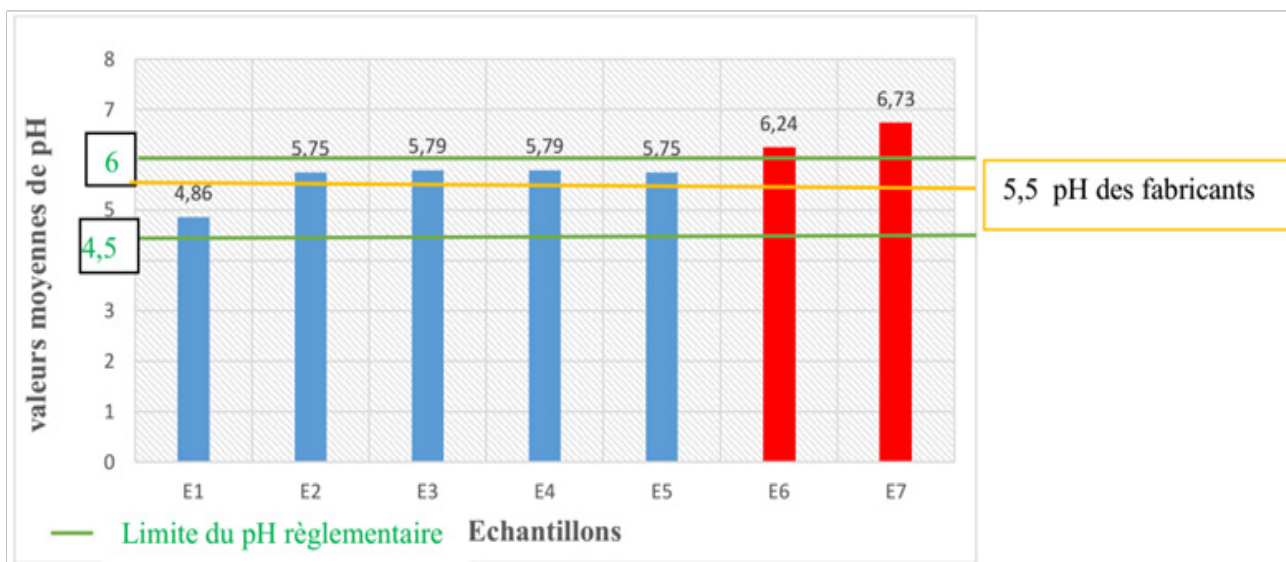


Figure 1 pH average values compared to the norm recommendation.

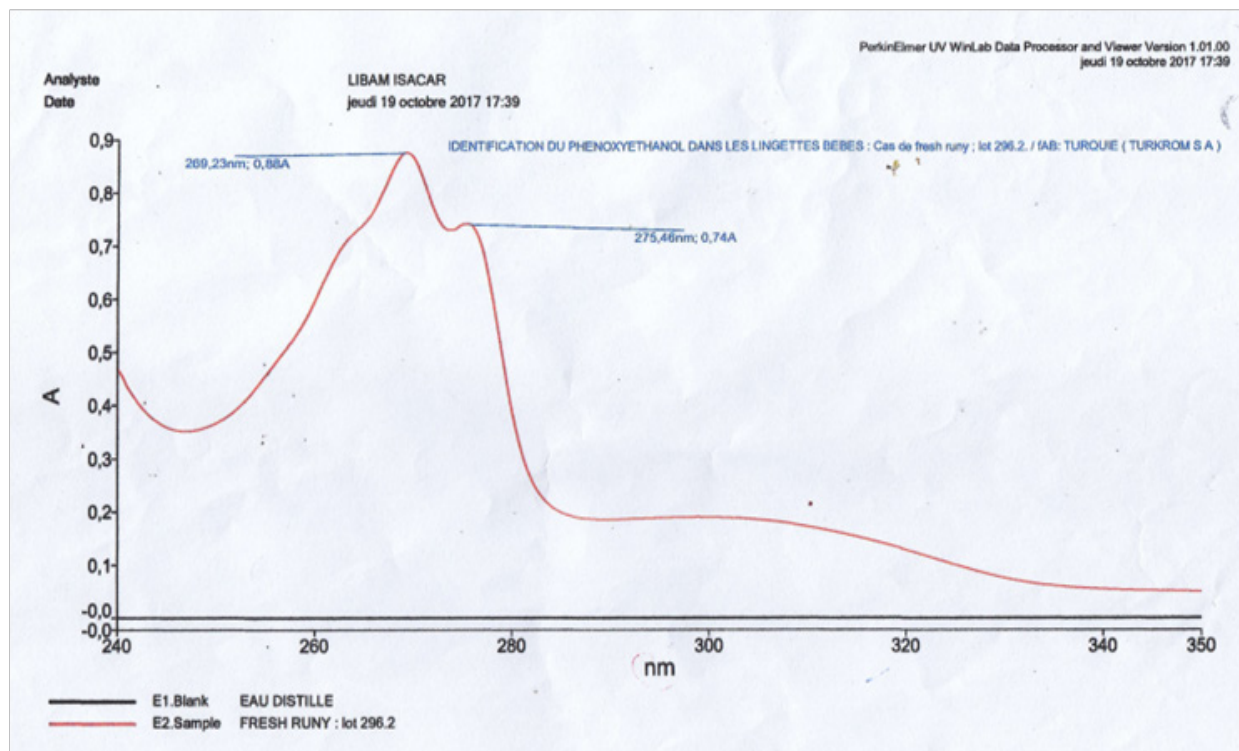


Figure 2 Some identification results of phenoxyethanol on UV spectrophotometer.

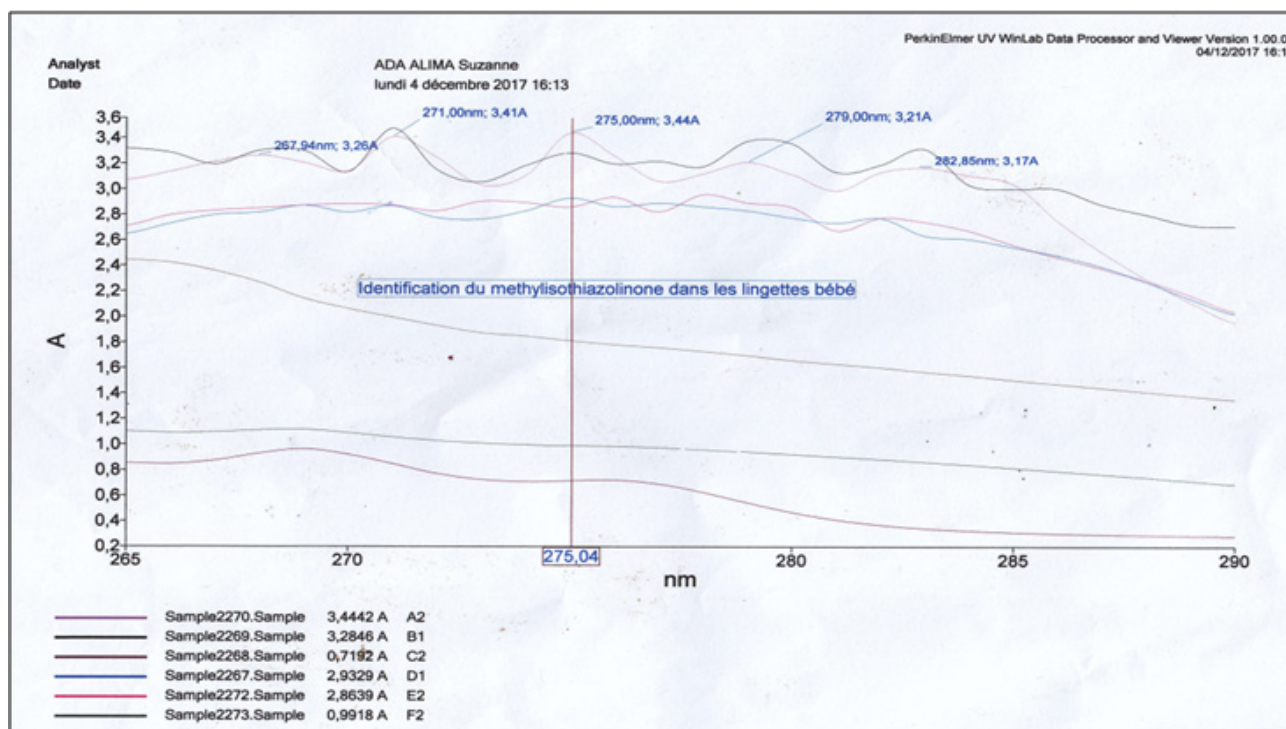


Figure 3 Some UV spectra for different MIT samples tested.

For each positive case, we determined the concentration of MIT (ppm) present in the wipes and calculated the safety margins (MoS) for each sample. The set results of the MoS are shown in Table 3.

Given all this values, the following can be outlined:

- a. The frequency use chosen (F=3, 6 and 15 wipes/day) cover the frequencies obtained during the investigation. Indeed the manufacturer did not indicate on the packaging the number of wipes to use daily. This variability in calculations allows us to determine the acceptable limit of daily use.
- b. Only 3 wipes/day of E1 has an acceptable safety margin (MoS): $103.42 > 100$ (the standard being strictly greater).
- c. For sample E5, at F=3, 6 and 15 wipes/day, the MoS is not acceptable, lower than the standard. This means that even within 3 wipes/day for E5, children remain at high risk of toxicity from MIT.
- d. MIT safety margin in wipes is unacceptable.

Table 3 Summary table of the MoS evaluation

Samples	E1			E2		
MMIT total (g)	0.000644			0.0000704		
Number of wipes	10			7		
MIT m per wipe (g)	0.0000644			0.0001006		
NOAEL (Mg/kg bw/day)	2			2		
Frequency of application day = F	3	6	15	3	6	15
SED (Mg/kg/day)	0.019338	0.038676	0.09669	0.0302	0.0604	0.151
MoS > 100	103,42	51,71	20,68	66.225	33.1125	13.26

Microbiological analysis

The identified microbiological conformity concerned 92.96% of the samples on TSA, 92.96% of the samples on PCA and 100% sample on Mueller Hinton agar. Regarding the microbiological stability, the

compliance rate was 85.71%. The level of microorganisms present in the baby wipes was 7.04% for the mesophilic aerobic germs, referring to *Staphylococcus aureus* (black and shiny colonies, Gram + shell, Catalase +, Coagulase +) after validation of the detection on Baird

parker agar and total absence of *Pseudomonas aeruginosa*. We also noted the presence of yeasts and molds at a rate of 7.04%, referring to *Candida albicans* (convex and creamy colonies, beige color) after validation of detection on SDA agar.

Summary of results obtained

For all tests, the Table 4 below provides a summary of results obtained in terms of conformities.

Table 4 Summary of overall compliance based on the results

Brands	Control of labeling	Physicochemical control				Microbiological control
		pH	Alcohol	Phenoxy ethanol	MIT	
E1	NC	C	NC	NC	NC	C
E2	NC	C	C	NC	C	C
E3	NC	C	C	C	C	NC
E4	NC	C	NC	C	C	C
E5	NC	C	C	C	NC	NC
E6	NC	NC	C	C	C	C
E7	NC	NC	C	NC	C	C

C, confirm NC, Not confirm

Discussion of results

The results of our survey showed that more than 8 in 10 (84.89% of the surveyed population) has never thought or even heard of wipes toxicity for their children. These results highlight a real need for public information. Indeed, if the small majority of the population (68 people out of 400, or 15.11%) has heard of the toxicity of baby wipes, knowledge remains generally sketchy and the information received is perceived as unsatisfactory for the most part. That ignorance of each other and this uncertainty is related to the poor communication and lack of awareness from healthcare organizations, added to the complexity of the product, as well they specified the Morocco Anti Poison Centers in its report in 2010.¹⁰

The labeling control result (100% of non-compliance) differs from that of the DGCCRF (Directorate General for Competition, Consumer Affairs and Fraud Control) in France, in 2011, which carried out checks on close to 8000 cosmetics, and detected over 600 cosmetic with a non-compliant labeling representing 7.5% of non-compliance of labeling. The information present on the label, contributes to traceability and product safety use. This allows us to say that any lack of essential information about the wipes label, reflects negligence on the part of manufacturers, as emphasized by ANSM in France² in its report on the safety of cosmetic products for children less than 03 years. Finally, the controls showed an increase of type “Free” claims (“allergen-free”, “paraben free”, “chlorine free”) some, incorrect or unfair allegations, likely to disturb the perception of the consumer. It is the same for highlighted ingredients “noble” as they appear in the composition sometimes extremely low rates.

For the 07 samples analyzed, 05 had a pH value located in the range of references (4.5 and 6), that is 71.43% of conformity against 28.57% Non-conformity. Note also that these measured pH values did not corresponded to those indicated on the label wipes (5.5). This result can be explained either by poor product quality (misrepresentation by the manufacturer on the pH of the final product) or by poor storage conditions in the retail outlets. According to the French Observatory of Cosmetics (OFC) in February 2018,¹¹ the pH values may decrease

or increase depending on storage conditions such as temperature, which is generally not specified by the manufacturer and even less respected by saling points. The test with Potassium dichromate is a method included in the European Pharmacopoeia 2008 for the detection of alcohol in products. For recorded positive tests (28.57%), one could read on about 50% of the samples the presence of alcohol. For the other (50%), the presence of alcohol has not been mentioned. This situation is even more serious when they notice that it's written on the positive samples controlled “alcohol free”.

Of the 07 samples examined, phenoxyethanol was detected in 03 samples (43%) and MIT in 02 samples (28.57% of the samples tested). These differ from those of the NGOs WECF published in 2016 after an investigation in France over 299 cosmetic products for babies.¹² They founded that the Methylisothiazolinone appeared in 19 products (6.3% of the tested products) and phenoxyethanol in 54 products (18.06% of the products tested). Similarly, French Consumers Union (UFC) in 2017¹³ had detected 23 products out of 1000 (2.3%) containing these two substances. It is also important to note that 01 of the 07 products (14.28%) contained both phenoxyethanol and MIT. Phenoxyethanol appear in the list of prohibited substances (1328 substances) or negative list (Annex II) of Cosmetic Regulation (EC) No 1223/2009.¹⁴ The dosage and the calculation of the MIT safety margin for the wipes were made when this ingredient still belonged to the list of substances subject to restriction (Annex III) of the cosmetics regulation, but since 27 January 2018 the MIT is a prohibited substance in cosmetics.¹¹

The microbiological compliance concerned 92.96% of the samples on TSA (meaning only 7.04% of total yeasts and molds count on TSA), 92.96% of the samples on PCA (meaning only 7.04% total aerobic mesophilic germ counts on PCA agar) and 100% sample on Mueller Hinton agar (absence of *Pseudomonas aeruginosa*). These results reflect the fact that manufacturers of 71.43% of tested samples met the good manufacturing practices (ISO 22716). Detected pathogenic microorganisms such as *Staphylococcus aureus* and *Candida albicans* are present small quantity, therefore complies with the standard (≤ 102 CFU/ml), but this number could increase if the storage conditions are not respected. As for the microbiological stability, the results

reflect the effectiveness of conservative utilities in 85.71% of the samples tested. As mentioned by some manufacturers, cosmetics and especially those who are used for a relatively long period, have an environment (temperature, pH and water) favorable to the development of microorganisms.¹⁵ (ISO/TS 11133-2/A1) incubated at 30°C for 5 days, the total aerobic mesophilic germ counts PCA agar (ISO 4833) incubated at 37°C for 72 h and *Pseudomonas aeruginosa* specific research on Mueller Hinton agar incubated at 37°C for 48 h.^{16–20}

Conclusion

In conclusion we can say that children's skin is fragile in structure and the seat area is an occlusive environment with significant application frequency of wipes (about 06 times per day). The non-compliance rate was 100% for labeling control, 71.43% for physicochemical tests with the presence of two forbidden substance detected namely phenoxyethanol (hepatotoxic, reproductive toxicity, hematotoxic) and Methylisothiazolinone (a contact allergen, the main cause of skin irritation in children), and 28.57% of non-compliance for microbiological testing. These non-conformities expose children to serious health problems including: a bacterial infection, allergies, skin irritations, physiological disturbances, aggravated by the presence of faces and urine. Faced with this worrying situation, it is mandatory that the competent authorities to focus on assessing the quality and safety of cosmetic products for children control the import of cosmetics, cosmetovigilance and are developing a national strategy for systematic control of cosmetic products in circulation in Cameroon and mass awareness about precautions to take regarding the use of these products.

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Conflicts of interest

Authors declare that there is no conflict of interest.

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