E-ISSN: 2790-6094
P-ISSN: 2957-4587

Journal Biological And Allied Health Sciences

Safety Assessment Of Over-The-Counter Personal Care And Cosmetic Products' Ingredients Based On Product Description And Properties

Original Article

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ARTICLE INFORMATION

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Key Words: Safety assessment, Over-the-counter (OTC), personal care and cosmetic products, Regulatory frameworks, Toxicity and carcinogenicity, Labeling transparency

ABSTRACT

Objectives: To assess the safety and health risk of ingredients in over the counter and personal care products focusing on safety standards and labeling.

Study Design: It was descriptive cross-sectional study.

Place and Duration of study : The study was conducted in Superior University for duration of 4 months.

Material and Methods: This study evaluated the safety of ingredients in over-the-counter personal care and cosmetic products. The evaluation is distributed among four categories: Hair care, eye care, skin care and cosmetics. A sample of 100 products were selected from pharmacies and online stores. Data is analyzed by using SPSS version 26, used statistical methods; descriptive statistics and Chi-square tests to determine toxicity, carcinogenicity, and labeling Compliance.

Results: The study examined that most of the products were safe in terms of toxicity and carcinogens, a significant number of products were deficient in key labeling information like; emergency contact details and usage instructions, emphasizing the importance of enhancing labeling to safeguard consumer safety and trust.Statistical significance of results are less then($p<0.05$) between safety level of ingredients and label adherence which mention gaps in regulation

Conclusion: The study underscores the critical need to enhance regulatory frameworks and raise consumer awareness. This study concludes that a considerable number of over-the-counter personal care and cosmetic products in Pakistan contain potentially harmful ingredients. Some products comply with safety standards, gaps in regularity and labeling transparency expose consumers to potential risk.

Introduction:

A wide range of goods used for grooming, personal hygiene, and aesthetic objectives are referred to as personal care products (PCP). These consist of items like moisturizers, deodorant, shampoo, toothpaste, soap, cosmetics, hair care products, and scents. These items are designed to be used externally to the skin, hair, nails, lips, and teeth in order to boost general well-being, improve attractiveness, and encourage cleanliness (1).

Over the years, the demand for cosmetics and personal care products has been rising constantly, demonstrating that customers all over the world use them (2)

It is anticipated that the cosmetics business would develop at a rate of about 900 billion yuan in 2023 (3). According to a survey, adult women use 27 cosmetics on average year, while adult males use 12 (4).

Skincare products were chosen by 22.5% of women and by 47.16% of men (5). Based on demographic data, research found that individuals between the ages of 19 and 23 are more likely to enjoy and use cosmetics (6). The use of cosmetic products is influenced by a number of variables, such as consumer behavior, buying choices, and the need to preserve one's self-esteem. It draws attention to issues about the impact of cosmetic ingredients on skin health, the rising demand for natural goods, and the importance of Malaysian Halal certification. It also looks at how cosmetics are used, such as whitening products, the impact of branding and marketing, and safety issues with chemical vs natural chemicals. Additionally covered is how regulatory frameworks affect consumer knowledge and ingredient safety (7).

A precise and unambiguous procedure is required to evaluate the effects of each substance in order to guarantee safety and efficacy. Knowing these substances' characteristics and descriptions is essential for safety evaluations. Market success depends on consumers being able to understand the advantages and performance of the product, which emphasizes the significance of thorough safety testing (8).A variety of substances found in personal care products (PCPs), such as skin, eye, and hair care products, may provide complicated safety risks. Additionally, more and more personal care products are using natural plant ingredients. Reviewing the safety evaluation of these products and chemicals while taking into account their regulatory status, possible health hazards, and consumer benefits is the goal of this thesis (9).

The phytochemical characterization of the plant source, possible contamination, adulteration, and hazardous residues are important factors to take into account when evaluating the safety of botanical substances added to personal care and

cosmetic products. Novel botanical PCP components can be compared using the parent plant or plants of the same species as comparators, much as genetically engineered plants. Read-across methods are made possible by chemical grouping, which estimates toxicological endpoints based on related compounds with comparable toxicities and physical/chemical characteristics. In order to evaluate trace compounds or minor ingredients, instruments such as the Threshold of Toxicological Concern (TTC) and Dermal Sensitization Threshold (DST) are used (10).

Although components used in cosmetics meet legal requirements, some substances are only allowed in very specific amounts because of the possibility of harm at high quantities. It's also critical to take into account the possibility of both immediate adverse reactions, such contact dermatitis and allergic reactions, and long-term effects (11)

Ensuring the safety of all substances used in common personal care and cosmetic items that are available without a prescription (over-the-counter products) is crucial for the customers' health and safety. As previously stated, a thorough and appropriate product review is essential because of the substantial usage of these items (8). It emphasizes how important these assessments are in order to prevent negative consequences from cosmetics. Thus, safety assessment may also contain standardized testing procedures, a regulatory framework for ingredient upgrades, the difficulties and suggestions, and safety evaluation (12).

A bill to mandate premarket safety testing for cosmetics, like that for pharmaceuticals, was proposed by the US Congress in the early 1970s. Alternative regulatory strategies were created even though the legislation was not passed. In order to protect customers' right to know about product safety, the FDA implemented labeling standards in 1975 with industry backing (13).

To assess the safety of preservatives based on published data, a decision tree method utilizing Weight of Evidence (WoE) and Integrated Approaches to Testing and Assessment (IATA) was used. To evaluate hazard levels (low, moderate, or high) and exposure pathways (local or systemic) for a number of endpoints, such as endocrine activity, carcinogenicity, mutagenicity, oral toxicity, phototoxicity, and skin and eye irritation, a toxicological matrix was developed (14).

Some goods, including skin-whitening creams, have high concentrations of hydroquinone (9%), which is 30 times higher than the acceptable limit of 0.3%. This increases the risk of cancer, genetic problems, allergic responses, and eye damage. In the context of increasing global demand of these products and safety concerns, the harmful chemicals that have serious hazardous effects are highlighted by analyzing these products. This study mention lack of studies and research deficiencies with respect to safety practices and labeling Compliance in Pakistan. To overcome this gap the evaluation is undertaken for the extensiveness of harmful ingredients, product labeling, safety measure and frameworks in Pakistan. The outcomes will present evidence based recommendations for policymakers and consumers for safety measures, regulatory frameworks and best practices (15).

Nano system will optimize the transport and durability of active and safe ingredients but regulatory system does not have ability to proper analysis of these systems. Nanosystems can improve product functionality, like the stability and distribution of active substances, they are becoming more and more common in cosmetic items. Notwithstanding their possible advantages, the application of Nano systems presents serious safety issues, especially in light of the paucity of thorough safety assessments for these innovative components in personal hygiene products. There may be loopholes in consumer protection since current regulatory frameworks have found it difficult to keep up with the quick growth of nanotechnology (16).

More sophisticated and effective techniques have been incorporated into the approach to cosmetic safety evaluation in recent years. The read-across (RAX) strategy is one such technique that is essential to next-generation risk assessments (NGRA) for cosmetic. NGRA astrain from animal testing and vitro testing. It focuses on safety of ingredients and sensitivity-based testing. NGRA Explains gap of harmful ingredients of personal care and cosmetic products in safety assessment. (17).

The Drug Regulatory Authority of Pakistan (DRAP) is in charge of making sure that cosmeceuticals are used responsibly and that they are safe, effective, and of high quality in Pakistan. However, the safety and efficacy of these products are seriously threatened by shortcomings in regulatory standards and execution, particularly in manufacturing and quality assurance. In order to address issues like the presence of heavy metals in cosmetics and guarantee consumer safety, DRAP must move quickly to enforce appropriate laws and good manufacturing practices (18).

In context of research aligning with Pakistan seems distributed or scattered. International markets follow strict rules, processes, standards and policies to maintain the standards and labeling of products. In comparison to international markets, when research on Pakistan's Regulatory framework is demonstrated it can be seen that it outlay both challenges and opportunities. It can be seen by a fact that as EU regulates detailed taxological examination or evaluation and regulatory compliance but unfortunately it sometimes relies on outdated safety protocol. Regulatory system is very strict in global like E.U and FDA it focusses on pre market testing and proper labelling for customer safety but in Local connection, Pakistan's Regulation system like DRAP is unable to fulfil these standards (19).

METHODOLOGY:

This study employed a descriptive cross-sectional survey to assess the safety of substances frequently found in the formulation of over-the-counter cosmetics and personal care products. Data was collected from various clinical settings, including Pharmacies (Mehmood Pharmacy, Servaid Pharmacy, Clinix + Pharmacy), Supermarkets (Hyper star, Metro Cash and Carry, Imtiaz Supermarket), Department Stores (AL Fatah, Haji Cream Baksh, enem shop) and online internet stores (Saloni.pk, Just4Girls.pk, Daraz.pk).

A total of 100 cosmetic and personal care items were examined for safety information and ingredient labels. The sample size was calculated using the formula $n = (Z_2 * p * (1 - p)) / E_2$, with values for n=100, 90 percent confidence level, Z=1.96, P=7% = 0.7, and E=0.05 as the error margin.

Stratified sampling was used to choose a representative sample of goods from various brands and categories, ensuring that frequently used components in over-the-counter personal care products were briefly evaluated. The study duration was four months after the synopsis was approved.

The selection criteria included items from various categories, such as makeup, skin care, hair care, and eye care, with available ingredient lists and labels. Products were excluded if they required a prescription or medical supervision, were designed for specific medical use, or contained substances deemed dangerous or prohibited by regulatory bodies.

This study prioritized consumers' health and safety, ensuring a comprehensive, objective, and law-abiding evaluation. Environmental effects were also considered to promote sustainable and ethical product formulation.

The preliminary lifecycle assessment (LCA) is conducted to evaluate ecological impact of personal care and cosmetic products to assess ingredient safety. This analysis actually provides sustainable environment of product formulation in the markets.

Further than toxicity and carcinogenicity, Dermal sensitization and cumulative exposure is incorporated in the analysis of study. Dermal sensitization was taken out from the available literature to notice the likelihood of allergic reactions on frequent exposure. Cumulative exposure was estimated and a more holistic view of consumer risk was estimated due to the simaltaneous usage of multiple products.

Data collection involved examining product labels and packaging, investigating ingredients using scientific resources, and evaluating each product. Data was arranged and examined to identify potential safety issues and areas for improvement in product formulation and labeling.

Data analysis was conducted using SPSS version 26, employing descriptive statistics and chi-square tests to determine frequently used ingredients and potential safety issues.

RESULTS:

A sample of OTC 100 PCP and cosmetic products are taken. Under these products four categories are made like 25 products from hair care products,25 from eye care products,25 from skin care products and 25 from cosmetic products and evaluated the safety of ingredients of all products by toxicity, carcinogenic effect, classified according to Globally harmonized system, label for specific skin type, first aid instructions or emergency contact information and any area for improvement.

Table 1: The comparison between ingredients of every category with every question is conducted using a cross-tabulation with a Chi-square test, as shown in the table

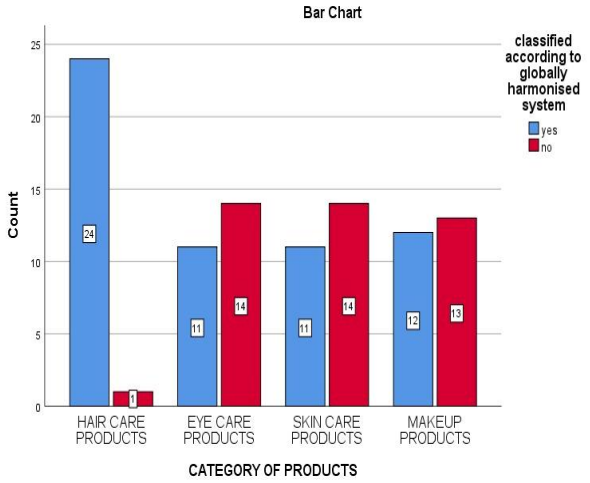
	Toxicity		Carcinogenic		Classified according to GHS		Label for specific skin types			First aid instructions on label			Any Area for Improvement		
	No	Yes	No	Yes	No	Yes	Agree	Neutral	Disagree	Agree	Neutral	Disagree	Yes	Neutral	No
HCP(Dimethicone,hydrolyzed keratin,pantathenol,salicyclic acid in low concentration and ceramide)	12 %	88 %	75%	25%	4%	96 %	44%	52%	4%	8%	36%	56%	92 %		8%
ECP(Diimethicone, retinol, caffeine, collagen and niacinamide)	56 %	44 %	84%	16%	56 %	44 %	100 %	0%	0%	12%	8%	80%	76 %		24 %
SCP(Niacinamide, retinol low in concentration, collagen ,aloe vera and ceramide)	56 %	44 %	88%	12%	56 %	44 %	44%	52%	4%	100 %			84 %		16 %
CP(Cyclopentasiloxane, dimethicone, retinol, niacinamide and pantathenol)	56 %	44 %	52%	48%	52 %	48 %	36%	36%	28%	0%	36%	64%	72 %		28 %
P Values	0.02		0.017		0.01		0.01			0.001			0.01		

This table presents a comparison of ingredient safety assessments across four types of personal care products. In hair care products, 88% of ingredients have undergone toxicity and safety testing, 75% are non-carcinogenic, and 94% are classified according to GHS standards. However, only 44% are labeled for specific skin types, and just 8% include first aid instructions. Overall, 92% require improvements in labeling for skin type specifications and emergency details. In eye care products, 44% of ingredients are tested, 84% are non-carcinogenic, and 100% are labeled for specific skin types. However, only 12% provide first aid instructions, with 76% needing enhanced labeling for toxicity and emergency details. In skin care products, 44% of ingredients are tested, 88% are non-carcinogenic, and all include first aid instructions. Despite this, 84% need better labeling regarding skin types and toxicity testing. For cosmetic products, 44% of ingredients are tested, 52% are non-carcinogenic, and 36% are labeled for specific skin types. No products contain first aid instructions, and 72% require labeling improvements. The p-values for all categories are below 0.05, indicating statistical significance.

In 81% of products follows the standards of GHS but they have not proper detail on label like first aid instructions, emergency contact information and warning signs for harmful ingredients but in comparison, EU regulations have detail label with emergency contact information and warning sign for harmful ingredients. So it is a proper policy gap in study.

E-ISSN: 2790-6094
P-ISSN: 2957-4587
Journal Biological And Allied Health Sciences

Figure 01: Bar Chart of Classified According To GHS



This bar chart shows how many products have been classified according to GHS and how many have not been classified according to GHS.

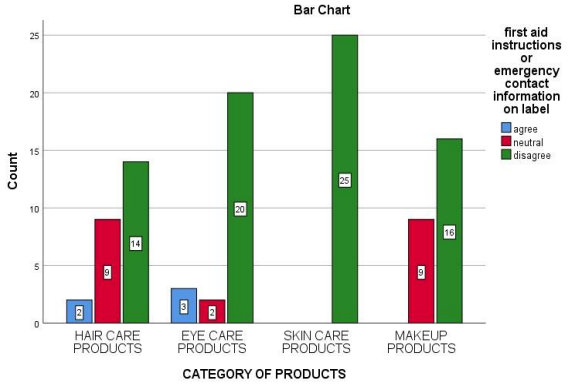
In Hair care products 22 products have been classified according to GHS (blue bar) , while 1 product have not been classified according to GHS(red bar).

In eye care products 11 products have been classified according to GHS(blue bar) , while 14 product have not been classified according to GHS(red bar).

In skin care products 11 products have been classified according to GHS (blue bar) , while 14 product have not been classified according to GHS(red bar).

In cosmetic products 12 products have been classified according to GHS (blue bar) , while 13 product have not been classified according to GHS(red bar).

Figure 02: Bar Chart of First Aid Instructions Or Emergency Contact Information On Label



This bar chart represents the availability of first aid instructions or emergency contact information on product label, categorized under three responses: agree, neutral and disagree.

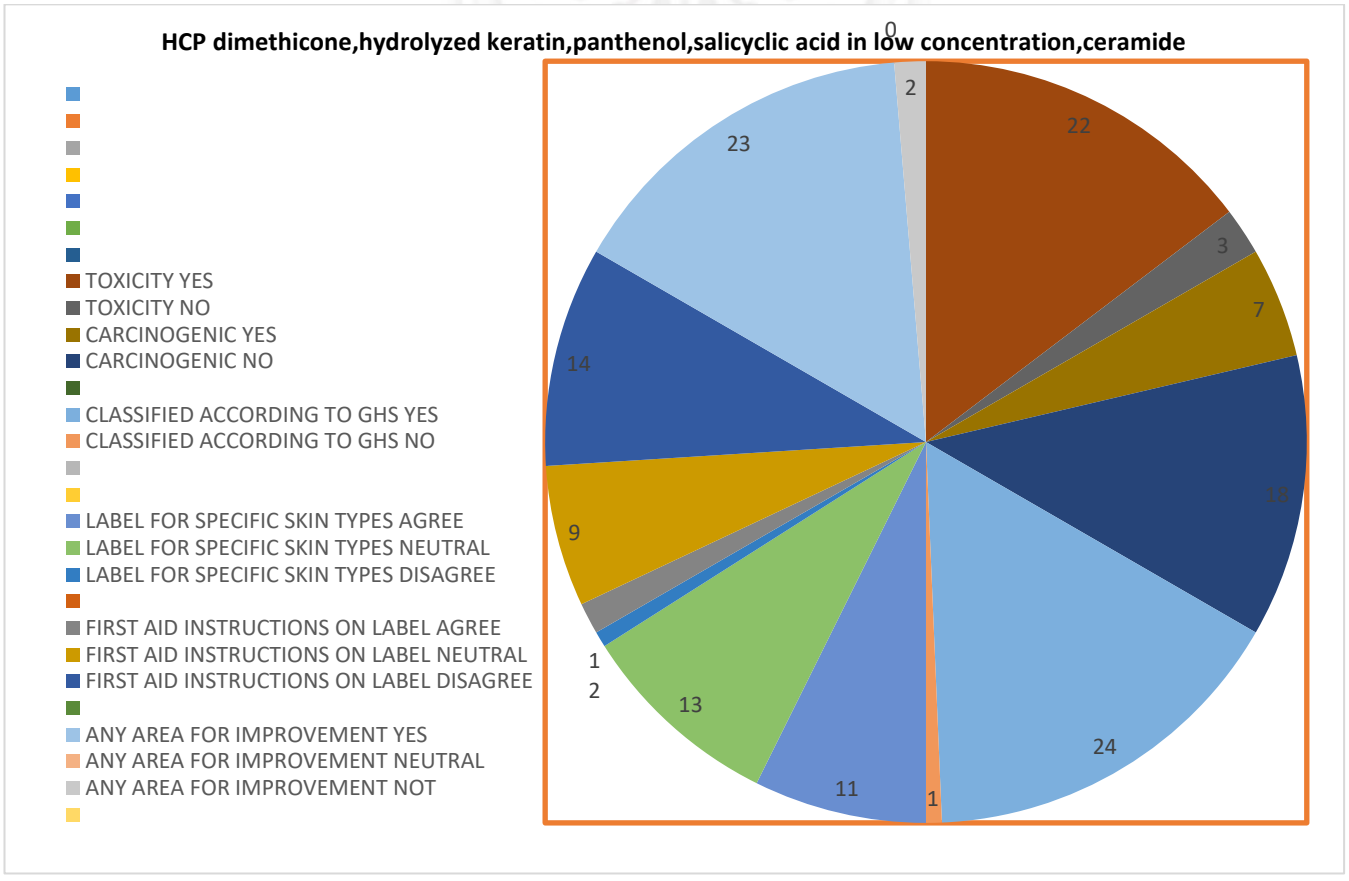
In Hair care products 2 are agree (blue bar) , 9 products are neutral(red bar) and 14 products are disagree(green bar).

In eye care products 3 are agree (blue bar) , 2 products are neutral(red bar) and 20 products are disagree(green bar) .

In skin care products All are disagree(green bar) .

In cosmetic products 9 products are neutral(red bar) and 16 products are disagree(green bar) .

Figure 03: The comparison between ingredients of every category with every question is conducted using a cross-tabulation with a Chi-square test, as shown in the figure below.



Out of the 100 products analyzed, 55 (55%) were found to be safe for toxicity, 74 (74%) were considered free of carcinogens, and 81 (81%) adhered to GHS classification standards. However, only 42 (42%) were suitable for different skin types, and 31 (31%) included proper labeling with emergency contact information and clear usage instructions. The results suggest that while most products met safety and classification criteria, there are notable shortcomings in labeling practices, especially in providing necessary instructions and emergency details. This underscores the need for enhanced safety labeling and greater compliance across products.

DISCUSSION:

The purpose of this study was to assess the safety of the ingredients in popular over-the-counter cosmetic and personal care products in Pakistan. In order to draw attention to the related health hazards and regulatory deficiencies, the emphasis was on determining the prevalence of potentially hazardous compounds, such as parabens, phthalates, heavy metals, and allergens. To guarantee a representative assessment across various product categories, including hair care, skin care, makeup, and eye care, a sample size of 100 goods was chosen using a stratified selection technique.

The investigation showed that the evaluated goods had different levels of safety. Ingredients like parabens, phthalates, and heavy metals, which have documented toxicological consequences such endocrine disruption and possible carcinogenicity, were present in a sizable percentage of items. These findings are consistent with other research, including that conducted by Bilal and Iqbal et al. (2019), which pointed out that common compounds present in over-the-counter personal care items, such as phthalates and parabens, have the potential to interfere with endocrine function. Similar to this, a study by Pogisego Dinake et al.(2023) examined the occurrence of dangerous chemicals in cosmetics, including heavy metals and phthalates, and emphasized regulatory oversight shortcomings. The study emphasized the significance of tighter production standards and better-quality control.

The analysis showed that the safety levels of the ingredients and product categories were statistically significantly correlated ($p < 0.05$). For instance, because they include potentially dangerous substances like arylamines and hydroquinone, hair dyes and skin-whitening lotions were classified as high-risk categories. These results align with those of McGregor et al. (2007), who expressed concerns regarding the safety of cosmetic ingredients, particularly hydroquinone and other compounds that have been limited in certain areas due to possible health dangers, such as cancer, birth defects, and developmental disorders. Cosmetic ingredients are governed by regulatory frameworks, such as those set forth by the EU and the U.S. Food and Drug Administration (FDA), although regional variations in rules call for close observation.

For hair care products, ingredients such as Dimethicone, Hydrolyzed Keratin, Pantothenol, Salicylic Acid (in low concentration), and Ceramide were found to be safe, while Sodium Lauryl Sulfate, Alcohol Denat, Synthetic Dyes, and Heavy Metals were unsafe due to irritation concern. In the case of eye care products, Dimethicone, Retinol, Caffeine, Collagen, and Niacinamide were deemed safe, while Hydroquinone, Parabens, and Retinol in high concentrations were identified as unsafe due to irritation and hormonal disturbance risks. For skin care product, Niacinamide, Retinol (in low concentration), Collagen, Aloe Vera, and Ceramide were safe, but Hydroquinone, Parabens, and Synthetic Fragrances raised concerns due to irritation and hormonal disturbance issues. In cosmetic products, ingredients like Cyclopentasiloxane, Dimethicone, Retinol, Niacinamide, and Pantothenol were safe, whereas Parabens, Alcohol Denat, and Synthetic Dyes were unsafe due to allergic reactions and long-term health risks.

The outcome of these findings are multifold. There are more than one perspectives under this study which includes consumer, industry and customers.In the perspective of consumer, inadequate labeling can direct adverse reactions and can deteriorate consumer assurance. For the industry, possibilities for both risk and opportunity can arise. By following best practices, comprehensive testing methods, safety regulations can ensure the safety of manufactures and consumers, it can enhance the reputation in market. It can also elevate competitive edge in global market. Moreover, to monitor the frameworks rigorously, advance methods such as next generation risk assessment and computational toxicology can modernize product safety evaluation.

This study adds to the expanding body of knowledge regarding the safety of cosmetic products and identifies important areas for regulatory and product formulation improvements. Future studies should concentrate on long-term health effects, including the effects of cumulative exposure and the possible "cocktail effect" of chemicals used in common products.

CONCLUSION:

The findings highlight the significance of strengthening regulatory frameworks, promoting safer product formulations and increasing consumer awareness. The safety and quality of personal care and cosmetic products can be greatly improved by addressing these issues. This study concludes that a significant number of over-the-counter personal care and cosmetic products in Pakistan contain potentially hazardous ingredients, and that while some products meet safety standards, gaps in regulatory enforcement and labeling transparency pose risks to consumer health.

The research focus on safety evaluation of ingredients based on product description and properties of over-the-counter products but in future, studies could focus on cumulative effect of repeated and low dose chemical exposure (like parabens, phthalates). So here is need to conduct longitudinal studies to check carcinogenic or mutagenic effects.

Authorize the insertion of emergency contact information and unambiguous usage instructions on labels. Moreover, For the product evaluations, usage of innovative methodologies like next generation risk assessment and computational toxicology is used. These methods will not only intricate the understanding

of chemical exposures but also demonstrate long-term health impacts precisely and accurately. Moreover, to validate current claims, the analysis of labeling with empirical chemical and toxicological testing is crucial. For the long term sustainability, it is suggested to follow the technique of revise and update regulatory frameworks to coordinate with international standards it will ensure both consumer safety and environmental sustainability in Pakistan.

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CONFLICT OF INTEREST

Authors declared no conflict of interest, whether financial or otherwise, that could influence the integrity, objectivity, or validity of their research work.

GRANT SUPPORT AND FINANCIAL DISCLOSURE

Authors declared no specific grant for this research from any funding agency in the public, commercial or non-profit sectors

DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request

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