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EXCIPIENTS IN COSMETIC SCIENCE: BALANCING FUNCTIONALITY AND TOXICOLOGICAL SAFETY - A CRITICAL REVIEW OF EMERGING FORMULATION STRATEGIES

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Abstract

The rapid expansion of the cosmetic industry and the increasing availability of personal care products have raised growing concerns regarding the toxicological safety of ingredients commonly used in cosmetic formulations.
Aim: This review aims to provide a comprehensive evaluation of the toxic potential of selected cosmetic ingredients and their associated health risks, focusing on systemic toxicity, endocrine disruption, developmental interference, respiratory implications, and carcinogenicity.
Methods: The analysis synthesizes recent toxicological studies, encompassing both short-term and long-term assessments, alongside a review of international regulatory frameworks governing cosmetic ingredient safety.
Results: Evidence indicates that several substances continue to be widely used in cosmetic formulations despite increasing data highlighting their potential adverse health effects. These include risks related to systemic toxicity, endocrine disruption, developmental effects, respiratory issues, and carcinogenicity.
Conclusion: The findings underscore the urgent need for enhanced scientific scrutiny, stricter regulatory policies, and a harmonized global approach to cosmetic safety. Ongoing research and reformulation strategies are critical to the development of safer cosmetic products and the advancement of more rigorous, transparent safety standards within the industry.

Keywords: Cosmetic ingredients, systemic toxicity, health risks, cosmetic formulations, regulatory oversight, Safety standards, toxicological studies, product reformulation

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Introduction

Over the past decades, the cosmetics and personal care industry has witnessed substantial growth, propelled by technological innovations, the pervasive influence of social media, and escalating consumer demand for products that not only enhance aesthetic appearance but also modulate the biological functions of the skin. In 2023, the global market for personal care products surpassed a valuation of 205 billion USD, with a projected annual growth rate of 4.5% for 2024 (Statista, 2025). It is estimated that more than 90% of individuals incorporate at least one cosmetic product into their daily routine. This trend is particularly pronounced among younger demographics; a survey in the United States revealed that over 70% of individuals aged 18 to 29 use cosmetic products daily, frequently influenced by social media trends, influencers, and digital marketing campaigns (Mintel, 2022).
Nevertheless, the widespread use of certain cosmetic ingredients has prompted significant safety concerns. Compounds such as parabens, phthalates, and per- and polyfluoroalkyl substances (PFAS) have been implicated as potentially toxic agents, linked to endocrine disruption, carcinogenicity, and adverse effects on reproductive development (Peaslee et al., 2021; Sunderland et al., 2019). Emerging research underscores the carcinogenic potential, endocrine-disrupting properties, and genotoxic risks posed by these substances, particularly under conditions of chronic exposure and bioaccumulation. Despite mounting evidence, only

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approximately 15% of cosmetic products undergo comprehensive long-term safety evaluations, including assessments for carcinogenicity, prior to market approval (Alnuqaydan, A. M., 2024). Moreover, the absence of harmonized international safety standards and regulatory deficiencies complicates consumer efforts to differentiate between safe and potentially hazardous products. This review critically examines the expanding utilization of cosmetic products by evaluating the toxicological profiles of their active ingredients and the health risks associated with exposure. It also highlights current regulatory shortcomings and advocates for more stringent safety assessments to safeguard consumer health in an increasingly crowded marketplace where cosmetic efficacy claims often intersect with biological effects.

Objective

This study aims to critically assess the toxicological risks posed by major ingredients in cosmetic products through a comprehensive review of existing literature on their short- and long-term effects. Additionally, it evaluates current regulatory safety standards and cosmetic formulations with an emphasis on identifying potential toxicities. Based on these findings, the study proposes recommendations to improve regulatory oversight and guide reformulation strategies for the development of safer cosmetic products.

Materials and methods

This review is based on a comprehensive analysis of scientific articles, regulatory reports, and toxicity assessments. Data were collected from academic databases such as PubMed, Scopus, and Google Scholar, focusing on studies published after 2020 that included keywords such as ‘cosmetic ingredients toxicity,’ ‘PFAS in cosmetics,’ ‘endocrine disruptors,’ among others. Articles were selected based on their scientific impact and relevance to the study topic.
This review encompasses:

- Toxicological studies examining the effects of common cosmetic ingredients (e.g., parabens, phthalates, PFAS, nanomaterials, microplastics, and heavy metals).
- Epidemiological data on human exposure levels to these chemicals.
- Regulatory guidelines and safety standards from organizations such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the World Health Organization (WHO).
- Case studies linking cosmetic products to adverse health outcomes

Results

From the numerous studies reviewed, some of the most debated cosmetic ingredients regarding their toxic effects on the body are presented below.

Parabens

Parabens are common preservatives used in cosmetic and personal care products to prevent the growth of bacteria and fungi. However, recent studies have raised concerns about their toxic effects. The toxicity of these preservative agents is a subject of debate even in pharmaceutical products, but in cosmetics, this issue becomes more serious, especially since most cosmetic products are used over extended periods and in repeated doses. Parabens (such as methylparaben, propylparaben, butylparaben, and ethyl paraben) share a structural similarity with estrogen, the female hormone. Due to this structural resemblance, they can bind to estrogen receptors in the body and mimic or interfere with hormonal signaling. Consequently, they can cause menstrual cycle disorders and increase the risk of breast cancer, as they tend to accumulate in body tissues (Sunderland et al., 2019). Traces of parabens have been detected in breast tumor samples (Darbre et al., 2020). Other studies have demonstrated their presence in hair samples, indicating exposure of individuals to parabens (Wojtkiewicz et al., 2021). Animal studies have shown that parabens may affect fertility, fetal development, and sperm parameters (in males). Exposure to butylparaben in mice resulted in reduced testosterone levels and testicular damage (Kumar et al., 2017). Moreover, long-term exposure has been associated with bioaccumulation of parabens in the organism. A study conducted on the U.S. population revealed the presence of parabens in blood, urine, and body tissues of many individuals. Paraben concentrations were found in the urine of 92% of the study participants (Calafat et al., 2010).

PFAS (Per- and Polyfluoroalkyl Substances)

These substances comprise a large group of synthetic chemicals widely used in industry due to their water-, oil-, and heat-resistant properties. In cosmetic products, PFAS are utilized to enhance texture, water resistance, even application on the skin, and product durability. Consequently, they are found in numerous cosmetic formulations such as eyebrow and eye makeup, waterproof mascaras, long-lasting lipsticks, BB/CC creams, facial creams that promise a "smooth finish," as well as liquid foundations. PFAS function by creating a thin, durable film on the skin or eyelashes, thereby increasing the product's resistance to water and sweat. A study conducted in North America detected high concentrations of fluorine in 52% of tested makeup products, clearly indicating extensive use of PFAS in cosmetics (Peaslee et al., 2021). However, recent studies reveal that some PFAS accumulate in the body over time (are bioaccumulative) and may interfere with the endocrine (hormonal) system. Even exposure at low levels can pose significant health risks, including liver damage, immune system suppression, and cancer development (The Lancet, 2023). PFAS are often referred to as "forever chemicals" because many do not naturally degrade in the environment, causing persistent pollution (Lunder & Andrews, 2021). One study assessed emissions of per- and polyfluoroalkyl substances from cosmetic use in the European Economic Area, identifying approximately 170 PFAS structures in cosmetic products, with polytetrafluoroethylene (PTFE) and C9-15 fluoroalcohol phosphate being the most common constituents (Pütz, Namazkar, & Benskin, 2022).

Phthalates and neurotoxicity

Phthalates are plasticizers frequently used in perfumes and other cosmetic products to enhance fragrance dispersion. Exposure to phthalates has been associated with developmental neurotoxicity and reproductive system damage. Phthalates are esters of phthalic acid widely used as plasticizers to soften plastics and improve fragrance distribution in cosmetic and personal care products. In cosmetics, they are commonly found in perfumes, hair sprays, body creams, nail polishes, and deodorants. Some of the most common phthalates include diethyl phthalate (DEP), dibutyl phthalate (DBP), and di(2-ethylhexyl) phthalate (DEHP) (Wang et al., 2021). Exposure to phthalates can occur dermally, through inhalation, or orally, especially when phthalates are released from packaging materials or cosmetic products onto the skin. These substances are recognized endocrine disruptors that interfere with hormonal functions, affecting brain development during critical periods, particularly during pregnancy. Studies have demonstrated that phthalates influence the expression of genes involved in neurogenesis and neuronal signaling by modulating estrogen and androgen receptors (Kundakovic & Champagne, 2021). Numerous epidemiological studies have reported correlations between elevated levels of phthalate metabolites in the urine of pregnant women and reduced intelligence quotient (IQ), memory problems, concentration difficulties, and increased impulsive behavior in children. A

recent meta-analysis including over 14 longitudinal studies found a strong association between prenatal phthalate exposure and decreased IQ scores in offspring (Kim et al., 2022).
A significant concern is the lack of accurate disclosure of phthalates on cosmetic product labels. For example, DEP is often included within “fragrance” or “parfum” components without being listed as a separate ingredient. An analysis of cosmetic products from European and Asian markets revealed that over 70% of perfumes contained detectable levels of phthalates (Gao et al., 2022)

Allergenic substances: Fragrance mix and Formaldehyde

Many synthetic fragrances consist of hundreds of chemical compounds, some of which are potent allergens or skin sensitizers. "Fragrance mix" and formaldehyde-releasing agents (such as quaternium-15) are among the most common causes of contact dermatitis (Thyssen et al., 2021). The "fragrance mix" is a standard blend of 8–12 aromatic compounds used in allergy testing, including cinnamal, eugenol, hydroxycitronellal, and isoeugenol. These substances are commonly found in perfumes, deodorants, shampoos, creams, and aftershave products. A recent systematic review indicates that fragrances are the most frequent cause of allergic contact dermatitis (ACD) in Europe, with a prevalence exceeding 10% in some tested populations (Uter et al., 2021). Studies show that repeated contact with these compounds, even at low levels, may lead to skin sensitization and the development of chronic dermatitis. Among the most problematic fragrance components is hydroxy-isohexyl-3-cyclohexene carboxaldehyde (HICC), which was banned by the European Union due to its high sensitization potential (ECHA, 2022).
Formaldehyde, a colorless gas with a strong odor, is used in some cosmetic products either in a bound form or released from preservatives such as quaternium-15, imidazolidinyl urea, and diazolidinyl urea. These substances are often employed to prevent bacterial and fungal growth in aqueous products. The World Health Organization’s International Agency for Research on Cancer (IARC) has classified formaldehyde as a Group 1 carcinogen, indicating sufficient evidence for its carcinogenicity in humans (IARC, 2021).
Based on data from the consulted studies, the distribution of potentially harmful ingredients in cosmetic products reveals significant concerns regarding consumer safety. Parabens represent the highest proportion, accounting for 35% of the identified substances. They are widely used as preservatives but have been linked to endocrine disruption and other health risks. Phthalates follow at 25%, known for their reproductive toxicity and frequent presence in fragranced products. Allergenic substances constitute 20% of the total, reflecting the widespread presence of sensitizing agents in cosmetics. PFAS, comprising 15%, are particularly concerning due to their environmental persistence and bioaccumulative nature. Lastly, other ingredients, representing 5%, encompass a variety of substances that may also pose health risks, albeit to a lesser extent. This distribution underscores the need for stricter regulatory oversight and reformulation efforts within the cosmetic industry. The chart below illustrates the distribution and percentage presence of the aforementioned excipients in cosmetic products.

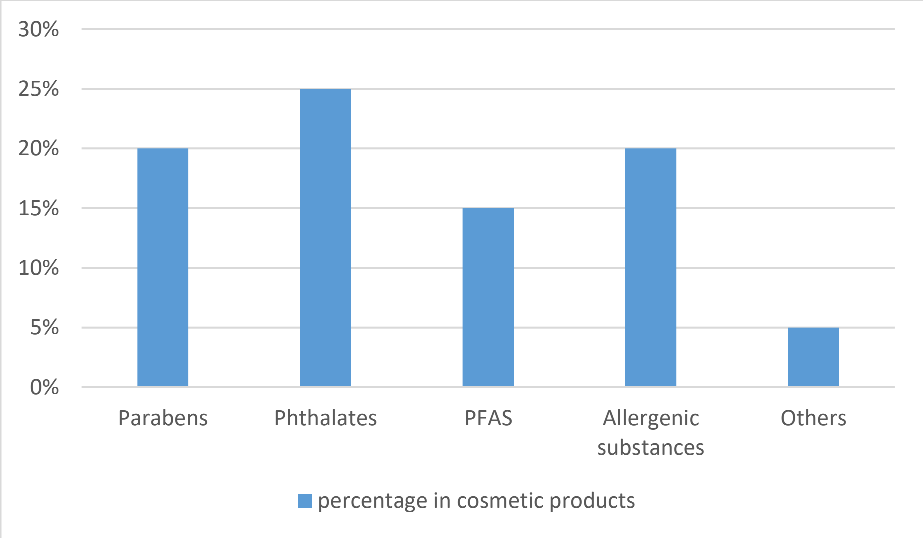

Figure 1. Distribution of potentially harmful ingredients in cosmetic products.

Nanomaterials and systemic risk

Nanotechnology is increasingly prevalent in cosmetics, particularly in sunscreen products (e.g., nano-TiO_2, nano-ZnO). Although generally considered safe for topical use, concerns remain regarding their penetration through damaged skin and potential accumulation in tissues. The application of nanotechnology in the cosmetic industry has led to significant advancements in improving the stability, bioavailability, and performance of active ingredients. The most commonly used nanomaterials include titanium dioxide (TiO_2) and zinc oxide (ZnO) nanoparticles, which serve as active UV filter components in sunscreen products. While most studies suggest a high level of safety for topical use on intact skin, concerns persist regarding penetration through compromised skin barriers, bioaccumulation, and possible systemic effects. Nanoparticles are particles with dimensions below 100 nm that, due to their small size and high surface area, have the potential to interact more intensively with the skin barrier and biological systems. Recent studies have shown that under conditions of skin damage (e.g., dermatitis, wounds, or after shaving), nanoparticles may penetrate through the upper layers and reach the dermis or even systemic circulation (Banerjee et al., 2022). A major concern regarding nanomaterials in cosmetics is their potential to increase oxidative stress, which can lead to DNA damage, inflammation, or apoptosis of skin cells. Specifically, nano-TiO_2, especially in its anatase form, has been reported to generate reactive oxygen species (ROS) under UV irradiation, contributing to possible cytotoxic and mutagenic effects (Wang et al., 2023).

The European Commission, through the Scientific Committee on Consumer Safety (SCCS), has issued updated guidelines supporting the use of nano-TiO_2 and nano-ZnO only in leave-on products at limited concentrations and provided they do not contain asbestos-type impurities or respirable particles (SCCS, 2021). For aerosol products, the risk of inhalation exposure to nanoparticles remains a significant concern.

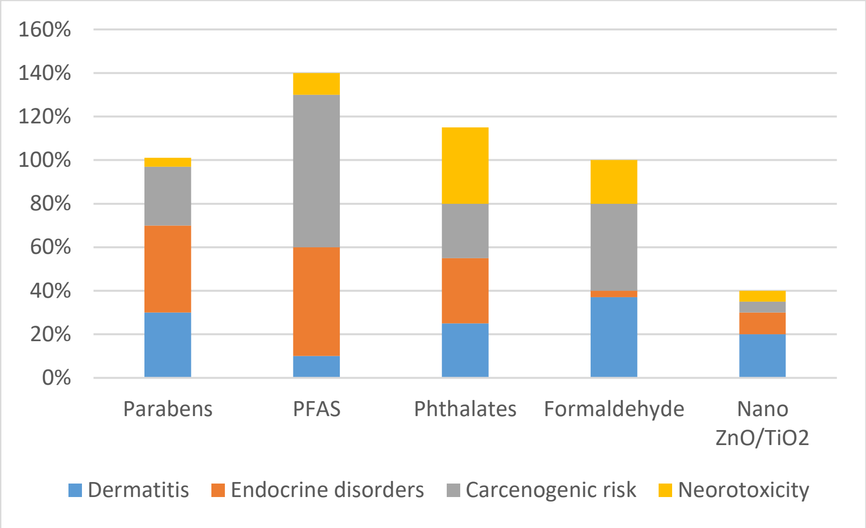

Fig.2 Health effects reported according to toxic ingredients

Microplastics and ecotoxicity

Microplastics (MPs) are plastic particles with dimensions smaller than 5 millimeters, which either serve intentional functions or arise as secondary byproducts from the degradation of larger plastic debris in the environment. In cosmetic formulations, microplastics are deliberately incorporated into a wide range of products, including exfoliating cleansers, scrubs, toothpastes, and makeup products, predominantly in the form of polyethylene (PE), polypropylene (PP), or nylon microspheres. These particles exhibit high resistance to environmental degradation, thereby posing substantial ecological risks. Recent investigations have demonstrated that microplastics may act as vectors for other toxic contaminants, facilitating their uptake by aquatic organisms and subsequent transfer through the food web (Smith et al., 2021). Although research into their biological effects is still at an early stage, microplastics have been detected in human fecal matter, blood samples, and even placental tissue, indicating a tangible potential for bioaccumulation within the human body (Leslie et al., 2022). The long-term health consequences of microplastic exposure remain largely uncertain; however, increasing evidence implicates these particles in the induction of oxidative stress, chronic inflammatory responses, and endocrine system disruption, warranting further investigation and precautionary measures.

Heavy metals in cosmetics

Heavy metals such as lead (Pb), cadmium (Cd), arsenic (As), mercury (Hg), and nickel (Ni) have been identified in numerous cosmetic products, including lipsticks, eyeliners, eyeshadows, powders, and foundations. These metals are not intentionally added to cosmetic formulations but enter as contaminants from mineral ingredients, pigments, or during manufacturing processes (Ali etal.,2022).

Exposure to heavy metals primarily occurs through prolonged skin contact, mucosal absorption (e.g., via lipsticks), and, in some cases, accidental ingestion. Although reported levels are often below established maximum permissible limits, daily and cumulative use over extended periods can lead to bioaccumulation, particularly in vulnerable populations such as pregnant women and children (Al-Salehetal.,2021).

A significant challenge in this area is the lack of standardized legal limits for heavy metals in cosmetics across many countries. Different nations enforce varying allowable thresholds, and in some cases, regulations are insufficient to adequately protect consumers from the effects of chronic exposure. The World Health Organization and other international bodies have called

for harmonization and the incorporation of regular testing for metallic contaminants in quality control protocols (WHO,2023).
To minimize risk, some manufacturers have transitioned to purified mineral pigments, implemented enhanced contaminant testing, and adopted purification technologies throughout the supply chain. The labeling “heavy metal-free” is becoming increasingly common, although an official mandatory certification remains absent in most markets.

Regulatory landscape and the imperative for stricter controls on toxic excipients in cosmetics

The well-documented toxicological concerns associated with excipients such as parabens, PFAS, fragrance allergens, formaldehyde donors, phthalates, nanomaterials, microplastics, and heavy metals have highlighted significant risks to human health and the environment, thereby underscoring the critical need for stringent and harmonized regulatory measures. While the European Union (EU) has implemented comprehensive restrictions, such as Regulation (EC) No 1223/2009 which limits parabens to a maximum concentration of 0.8% and bans certain types entirely, other regions, notably the United States, lack comparable binding standards, relying largely on voluntary monitoring and guidance by the Food and Drug Administration (FDA) (European Commission, 2009; FDA, 2023). Similarly, persistent organic pollutants such as per- and polyfluoroalkyl substances (PFAS) are subject to progressive bans in the EU under the REACH regulation (EC No 1907/2006), whereas North American regulations remain insufficiently stringent, leading to potential consumer exposure risks (ECHA, 2023; FDA, 2022). Additionally, allergenic fragrance compounds, formaldehyde releasers, phthalates, nanomaterials, microplastics, and heavy metals are variably regulated, with many jurisdictions lacking comprehensive labeling, concentration limits, or testing requirements (SCCS, 2020; WHO, 2022; California State Legislature, 2018). This regulatory patchwork complicates consumer safety assurance and allows for the bioaccumulation of harmful substances, particularly affecting vulnerable populations such as pregnant women and children (Al-Saleh et al., 2021). Hence, international organizations including the World Health Organization and the European Chemicals Agency advocate for globally harmonized standards, mandatory ingredient disclosures, rigorous safety evaluations, and enforceable limits to effectively minimize toxicological risks associated with cosmetic excipients (WHO, 2023; ECHA, 2020). Without such measures, the continued presence of these hazardous substances threatens public health and environmental safety.
The table below summarizes the existing legislative framework regulating toxic excipients in cosmetic products, including parabens, PFAS, fragrance components, formaldehyde and its donors, phthalates, nanomaterials, microplastics, and heavy metals. It outlines the main regulations and restrictions established by international and national authorities, along with the relevant references. Additionally, the table highlights gaps and deficiencies in legislation, particularly in jurisdictions where standards are inadequate, fragmented, or where specific regulations are entirely absent, posing significant challenges to consumer safety and environmental protection.

Tab. 1 Summary of existing regulatory frameworks and gaps for toxic excipients

Toxic Excipient	Key Regulations and Restrictions	Jurisdiction / Organization	Year / Reference	Gaps or Challenges in Regulation
Parabens	Restrictions on total concentration (max 0.8%) and bans on certain parabens (e.g., isopropylparaben)	EU (Regulation (EC) 1223/2009)	SCCS Opinion (2021); EC 1223/2009	No full legal bans in the US; monitoring and lack of detailed concentration standards (FDA, 2023)
PFAS	Progressive bans on usage, especially in the EU. Detailed composition reporting required	EU (REACH Regulation (EC) 1907/2006), US (FDA)	EC REACH (2023); FDA Guidance (2022)	US and Canada have weaker or incomplete regulations for PFAS in cosmetics
Fragrance Mix	Mandatory declaration of allergens on labels; concentration limits	EU (Regulation (EC) 1223/2009), FDA	SCCS Opinion (2020); WHO (2022)	Lack of global harmonization; many non-EU countries do not require full disclosure
Formaldehyde and Donors	Maximum concentration limits (e.g., max 0.2%) in rinse-off products	EU (Regulation (EC) 1223/2009), US (FDA)	EC 1223/2009; FDA (2022)	Some countries lack strict control and detailed testing protocols
Phthalates	Bans on certain phthalates (DEHP, DBP, BBP); restrictions on others	EU (REACH), US (CPSIA)	REACH (EC 1907/2006); CPSIA (2008)	US has partial restrictions; lacks comprehensive standards for all phthalates in cosmetics
Nanomaterials	Mandatory registration and labeling; compulsory safety assessment	EU (Reg. 1223/2009, Annexes), ECHA	SCCS Opinion (2021); ECHA Guidance (2020)	Many countries outside the EU lack specific regulations for nanomaterials in cosmetics
Microplastics	Gradual bans on microplastics in exfoliants and other products	EU (Regulation 2022/XXX), US (proposed legislation)	EU (2023); California Microbead Ban (2018)	No comprehensive global bans or enforcement; US legislation still in proposal stage
Heavy Metals	Strict limits for Pb, Cd, Hg, As, Ni; maximum permissible levels	EU (Reg. 1223/2009), US (FDA), WHO	EC 1223/2009; FDA (2023); WHO Chemical Safety (2023)	Lack of global harmonization; limits vary widely by country; some countries lack systematic testing

Innovative formulation strategies: balancing safety and sustainability of synthetic and natural excipients

In response to increasing concerns regarding the toxicity and environmental impact of conventional excipients such as parabens, PFAS, phthalates, microplastics, and heavy metals, the cosmetic industry is progressively implementing innovative formulation strategies aimed at reducing or eliminating these substances. A key strategy involves replacing harmful synthetic excipients with safer, naturally derived alternatives, including plant-based preservatives, essential oils, and biodegradable polymers, which offer comparable efficacy with potentially lower health risks (Silva et al., 2021). Nonetheless, the safety of natural excipients is also subject to rigorous evaluation, as some natural compounds may provoke allergic reactions or exhibit variable chemical compositions that influence product stability and toxicity (Johnson & Lee, 2022). Advances in green chemistry and nanotechnology further enable the design of targeted delivery systems that enhance product stability and bioavailability while minimizing the use of potentially hazardous excipients (Kumar & Singh, 2022). Additionally, the movement toward "clean label" formulations emphasizes transparency and consumer safety, supported by comprehensive toxicological screening and compliance with evolving regulatory requirements (Lee et al., 2023). These approaches address both consumer demand for sustainable and non-toxic personal care products and the necessity of ensuring safety and efficacy for all excipients, whether natural or synthetic (Gonzalez & Ramirez, 2020). Continued interdisciplinary research and collaboration among industry stakeholders, academia, and regulatory bodies remain essential for advancing the development of safer and more sustainable cosmetic formulations.

Conclusion

The widespread and daily use of cosmetic products exposes consumers to a broad range of chemical substances, some of which possess significant toxicological potential. Evidence gathered from contemporary literature indicates that ingredients such as parabens, phthalates, PFAS, and certain fragrances or colorants may exhibit endocrine-disrupting, carcinogenic, allergic, or bio-accumulative effects in the human body. Although most of these substances are permitted within limits set by regulatory authorities, the lack of global harmonization and gaps in labeling transparency pose a serious challenge to consumer safety. Consequently, there is an urgent need for continuous review of risk assessments and for improving control mechanisms and public information.

Proposed measures

1. Strengthening regulations concerning ingredients with toxic potential by harmonizing international standards and imposing stricter limits on high-risk substances (e.g., PFAS, long-chain parabens).
2. Mandatory disclosure of all ingredients on cosmetic labels, including all components such as fragrance agents and possible contaminant by-products (e.g., 1,4-dioxane, formaldehyde).
3. Implementation of mandatory toxicological testing for finished products, not only for individual ingredients, to evaluate synergistic or combined effects.
4. Promotion of the use of natural, biocompatible, and biodegradable ingredients through subsidies and incentives for innovation in the cosmetic industry.
5. Establishment of a publicly accessible database on cosmetic ingredients and their toxicity to enable informed consumer choices and enhance transparency.

6. Consumer awareness campaigns regarding the potential risks of certain ingredients and education on interpreting cosmetic labels.

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