Chapter 3

From Invisible Risks to Visible Responsibilities: Manufacturing, Safety, Health Impacts, and Ethics in Cleaning and Cosmetic Products

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Abstract

Cleaning agents and cosmetic products are widely used consumer commodities, associated with continuous and heterogeneous human exposure in diverse settings. Ensuring their safety requires a comprehensive approach that integrates formulation design, raw material qualification, Good Manufacturing Practices (GMP), physicochemical and microbiological quality control, stability testing, and accurate labeling. In Türkiye, cosmetic products are regulated under the Cosmetic Products Regulation, which is fully harmonized with European Union Regulation (EC) No. 1223/2009. This regulatory framework establishes core obligations, including pre-market notification and maintenance of a Product Information File (PIF). In contrast, household cleaning products follow distinct regulatory pathways depending on their intended use. Products with biocidal claims (e.g., disinfectants) require authorization under the Biocidal Products Regulation. This chapter provides a structured, evidence-based overview of GMP-driven manufacturing, critical safety and performance testing strategies, key human health endpoints—particularly dermal sensitization and respiratory effects—and ethical aspects of production, including non-animal testing approaches, transparency, and sustainability.

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1. Introduction

Cosmetic and cleaning products constitute a significant class of consumer goods that generate low-dose, cumulative exposure throughout daily life via repeated contact with the skin, hair, mucous membranes, and the respiratory tract. Product safety, therefore, extends beyond simplistic assertions of "harmlessness". Instead, it involves the systematic identification, evaluation, and management of potential risks, including skin and eye irritation, sensitization, inhalation-related toxicity, and long-term cumulative effects under reasonably foreseeable conditions of use. Accordingly, manufacturing processes cannot be considered in isolation; they must be integrated within a comprehensive framework encompassing Quality Assurance (QA), Quality Control (QC), full traceability, cosmetovigilance systems, and effective recall mechanisms to ensure sustained consumer safety and regulatory compliance (Turkish Official Gazette, 2023).

Current evidence suggests that contact allergens, particularly certain preservatives and fragrance constituents, are significant contributors to Allergic Contact Dermatitis (ACD) in both consumer and occupational settings (Aerts et al., 2017; Alinaghi et al., 2019). Additionally, exposure to chemical aerosols and volatile organic compounds (VOCs) generated during cleaning activities has been linked to a long-term decline in respiratory function (Svanes et al., 2018). Within this framework, safety assessment and ethical responsibility necessitate a shift beyond mere regulatory compliance toward the adoption of a precautionary design principle.

2. Regulatory Framework and Market Access for Cosmetic and Cleaning Products in Türkiye

2.1. Cosmetic Products: Legislative Requirements, Notification Procedures, and the Product Information File (PIF)

The Cosmetic Products Regulation in Türkiye has been enacted in complete alignment with European Union Regulation (EC) No 1223/2009 (Turkish Official Gazette, 2023). This regulatory framework clearly delineates the legal responsibilities of the Responsible Person, defines the methodology for assessing the safety of cosmetic products, establishes the minimum requirements for placing products on the market, and outlines mandatory labeling provisions.

In practical terms, regulatory compliance is ensured through product notification via the national electronic database, the Product Tracking System (Ürün Takip Sistemi, ÜTS), and the preparation and maintenance

of a comprehensive Product Information File (PIF). The PIF serves as an auditable technical dossier containing detailed information on product formulation and composition, raw material specifications, manufacturing processes, documentation of compliance with Good Manufacturing Practices (GMP), microbiological quality and stability data, packaging compatibility and conformity, records of undesirable effects, and the Cosmetic Product Safety Report (CPSR).

2.2. Distinguishing Cleaning Products from Biocidal Products

From a regulatory perspective, cleaning products do not constitute a homogeneous category; instead, their legal classification is determined primarily by the product's intended purpose and the claims made by the manufacturer. Products that explicitly claim to prevent, control, or eliminate microorganisms—such as those intended for disinfection or antiseptic use—are classified as biocidal products and fall under the scope of the Biocidal Products Regulation. These products are therefore subject to rigorous authorization, registration, and efficacy evaluation requirements prior to market placement (Legislation Information System, 2009; Turkish Medicines and Medical Devices Agency [TİTCK], n.d.).

By contrast, cleaning agents intended solely for the physical removal of dirt, grease, or residues, and that do not carry biocidal or antimicrobial claims, are regulated within the general product safety framework and, where relevant, under specific detergent legislation. Within the biocidal regulatory regime, products are assessed according to a product-type-based classification system, including, for example, Product Type 1 (human hygiene) and Product Type 2 (disinfection of surfaces).

3. Manufacturing Processes: GMP-Driven Design and Operational Control

In the cosmetics sector, Good Manufacturing Practices (GMP) are governed by ISO 22716, a standard published by the International Organization for Standardization (ISO). The overarching objective of GMP is to ensure that cosmetic products are consistently manufactured and controlled in accordance with predefined quality requirements, thereby minimizing the risks of contamination, mix-ups, and deviations, while maintaining full traceability throughout the entire production lifecycle (ISO 22716:2007).

Within a GMP-based manufacturing framework, several critical control elements can be identified:

- **Raw Material and Supplier Management:** Verification of raw material identity, purity profiles, impurity limits, including heavy metals, and microbiological quality against established specifications, together with supplier qualification and continuous performance monitoring.
- **Process Control and Hygiene:** Implementation of validated equipment cleaning and sanitization procedures, including Clean-in-Place (CIP) and Sterilize-in-Place (SIP) principles; comprehensive batch documentation; line clearance procedures; systematic assessment of cross-contamination risks; and routine environmental monitoring, encompassing water quality and air hygiene.
- **Filling and Packaging Control:** Evaluation of packaging material compatibility, assessment of potential migration and interaction risks, verification of container–closure integrity, confirmation of fill volume and dosage accuracy, and controlled application of batch numbering and expiration date labeling.
- **Product Release Criteria:** Final product release based on the evaluation of Quality Control (QC) test results, structured handling of Out-of-Specification (OOS) findings, and implementation of appropriate Corrective and Preventive Actions (CAPA).

4. Testing Strategies for Safety and Quality

4.1. Physicochemical Testing and pH Management

pH is a critical quality parameter, particularly for topical products, as it directly influences the potential for irritation and the functional integrity of the skin barrier. Although the physiological pH of the skin surface is slightly acidic, typically ranging from 4.5 to 5.5, product mildness cannot be evaluated solely based on pH. Instead, it should be assessed in conjunction with the surfactant system, solvent composition, overall formulation matrix, and the intended mode of application (Abels & Angelova-Fischer, 2018).

By contrast, household cleaning products may be formulated at extreme pH values to meet specific performance requirements, such as alkaline formulations for grease removal or acidic products for scale dissolution. In these cases, safety is achieved not through physiological compatibility but through defined concentration limits, clear and restrictive instructions for use, and appropriate hazard classification and labeling.

4.2. Microbiological Quality and Preservative Efficacy

Microbiological contamination represents a significant risk to both product integrity and consumer health, particularly for products intended for application in the periocular region or on mucous membranes. To mitigate these risks, several international standards provide the methodological and regulatory framework for the assessment of microbiological quality in cosmetic products:

- **ISO 17516:2014**, which establishes acceptable microbiological limits for finished cosmetic products;
- **ISO 11930:2019**, which specifies the methodology for preservative efficacy testing (PET), commonly referred to as the challenge test;
- **ISO 29621:2017**, which guides microbiological risk assessment and the identification of products considered to present a low microbiological risk.

Although many household cleaning products possess intrinsic inhibitory factors, such as extreme pH values or low water activity, water-based formulations may still support microbial survival or become contaminated during use. Consequently, appropriate preservation strategies remain essential to ensure microbiological stability and shelf life throughout the intended period of use.

4.3. Stability, Shelf Life, and Packaging Compatibility

Stability testing is designed to evaluate the physical and chemical integrity of products over time. Physical stability assessments typically address parameters such as viscosity drift, phase separation, and changes in color or odor. In contrast, chemical stability focuses on the degradation of active ingredients and pH drift. Additionally, potential interactions between the formulation and its packaging, including adsorption, migration, and permeability, must be systematically evaluated, as these factors can directly impact product performance and safety.

ISO/TR 18811:2018 provides comprehensive guidance on the design, conduct, and interpretation of stability studies for cosmetic products. For cleaning products, particular attention must be paid to the stability of oxidative agents, such as hypochlorite and peroxides, since their degradation may compromise both product efficacy and the reliability of the assigned shelf life.

4.4. Dermatological Safety: Differentiating Irritation and Sensitization

Cutaneous adverse reactions associated with cosmetic and cleaning products are generally classified according to two primary pathogenic mechanisms. Irritant Contact Dermatitis (ICD) arises from direct damage to the skin barrier and subsequent non-specific inflammatory responses, most commonly linked to high surfactant concentrations, organic solvents, or formulations with extreme pH values. In contrast, Allergic Contact Dermatitis (ACD) represents an immunologically mediated response elicited by specific sensitizing substances, with preservatives—particularly isothiazolinones—and fragrance allergens identified as the predominant risk factors.

Systematic reviews have established that contact allergy constitutes a significant and widespread public health concern (Alinaghi et al., 2019). Among sensitizers, isothiazolinone derivatives, such as methylisothiazolinone (MI), are of particular concern due to their high potential for sensitization in both industrial and cosmetic contexts (Aerts et al., 2017; Wilford & de Gannes, 2017). Consequently, dermatological safety assessments must incorporate quantitative risk characterization, including the calculation of the Margin of Safety (MoS), based on realistic aggregate exposure scenarios.

5. Safety and Performance Requirements by Product Type

Table 1. Comparative analysis of quality and safety requirements across product categories

Area of Assessment	Cosmetic & Personal Hygiene Products	Household Cleaning Products	Biocidal Products (Disinfectants)
Regulatory Approach	Product notification, Product Information File (PIF), and cosmetic safety assessment in accordance with national regulations (TİTCK, 2023).	Dependent on claims; subject to chemical safety and labeling regulations (CLP/SEA).	Licensing and registration; assessment based on product type and demonstrated efficacy (Legislation Information System, 2009).
pH Suitability	Physiological compatibility is the primary objective; pH alone is insufficient to ensure safety (Abels & Angelova-Fischer, 2018).	Wide pH ranges are permitted to achieve performance objectives; effective risk communication is essential.	Formulation-dependent; skin tolerability is critical for Product Type 1 (human hygiene) products.
Microbiological Quality	Compliance with the limits defined in ISO 17516.	Spoilage risk management is required for water-based formulations.	Microbial contamination may compromise both efficacy and safety.

Preservation	Verified through preservative efficacy testing (Challenge Test; ISO 11930).	The preservative system is verified where necessary.	Stability of the active substance is the primary concern.
Stability	Accelerated and real-time stability testing, including packaging compatibility (ISO/TR 18811).	Degradation of active substances and integrity of the packaging barrier are critical.	Efficacy and safety claims must remain valid throughout the declared shelf life of the product.
Dermal Safety	Strong emphasis on the management of contact allergy (ACD) (Alinaghi et al., 2019).	Risk of irritation in concentrated formulations; personal protective equipment (PPE) instructions are required.	Evaluation of irritation and sensitization potential is mandatory.
Respiratory Exposure	Inhalation toxicity is considered for spray and aerosol formulations.	High risk is associated with volatile compounds; long-term declines in lung function have been reported (Svanes et al., 2018).	Inhalation and ocular exposure represent significant risks associated with spray disinfectants.
Labeling	INCI list, instructions for use, warnings, and traceability information.	Hazard pictograms, dilution instructions, and child safety warnings.	Instructions must strictly correspond to authorized claims and risk mitigation measures.

6. Human Health Impacts: Evidence-Based Risk Areas

6.1. Dermal Effects: Irritation and Allergy

Cosmetic and cleaning formulations often contain surfactants and functional additives that can compromise the skin's integrity. Irritant effects are typically dose-dependent and closely linked to the frequency and duration of exposure, whereas allergic responses are substance-specific and mediated via immunological mechanisms. The high prevalence of contact allergy in the general population highlights the crucial importance of meticulous ingredient selection and transparent labeling practices. These measures should be considered not merely as regulatory obligations but as essential public health imperatives (Alinaghi et al., 2019).

6.2. Respiratory System: Long-term Outcomes of Cleaning

Cleaning activities generate a variety of reaction products, aerosols, and volatile organic compounds (VOCs), including chloramines. Evidence from longitudinal cohort studies has demonstrated a significant association between regular cleaning activities—both domestic and occupational—and accelerated decline in lung function, with effects reported to be particularly pronounced in women (Svanes et al., 2018). These findings suggest that spray-based formulations and inadequately ventilated environments require prioritized risk communication, alongside the implementation of targeted respiratory protection programs.

7. Labeling, Claim Management, and Transparency

Labeling serves as the primary interface for risk communication between manufacturers and end users. In cosmetic products, labeling requirements include the complete ingredient list (INCI), instructions for use, and identification details of the responsible person. For household cleaning products, labeling must clearly and unambiguously convey critical safety information, including dilution instructions, emergency procedures for eye or skin contact, and explicit warnings against mixing incompatible chemical agents, such as bleach and acidic substances.

Product claims—such as "hypoallergenic," "dermatologically tested," or "antibacterial"—may be misleading if not substantiated by robust scientific evidence. Consequently, ethical claim management should be considered an integral component of product stewardship, extending beyond regulatory compliance to encompass consumer protection and public trust.

8. Occupational Health and Safety (OHS)

Occupational health and safety in production and laboratory environments should be managed according to the hierarchy of controls, including substitution, engineering controls, administrative measures, and the use of personal protective equipment (PPE). Core preventive measures encompass adequate general ventilation and localized exhaust systems for the management of volatile solvents; the use of chemical-resistant PPE, such as gloves, goggles, and face shields, when handling acids, alkalis, and oxidizing agents; the establishment of comprehensive chemical spill response procedures; and strict adherence to Safety Data Sheets (SDS).

Moreover, the respiratory risks associated with aerosolized substances necessitate the implementation of targeted respiratory protection programs

for workers engaged in filling, packaging, and production operations (Svanes et al., 2018).

9. Ethical Dimensions and Sustainability

Ethical production extends beyond mere regulatory compliance to include the proactive mitigation of foreseeable harm and a commitment to long-term sustainability. Within this framework, several key pillars underpin responsible product stewardship.

Non-animal testing strategies are a cornerstone of contemporary cosmetic safety science, with the increasing adoption of validated in vitro and in silico methodologies, complemented by weight-of-evidence (WoE) approaches, which enable hazard assessment while upholding ethical imperatives. Safer ingredient selection represents a parallel priority, achieved through the substitution of potent sensitizers, reduction of excessive fragrance loads, and formulation strategies specifically designed for sensitive or vulnerable populations, thereby contributing to a decreased burden of allergic contact dermatitis (ACD).

Environmental responsibility also entails minimizing the product life-cycle footprint through the use of concentrated formulations, biodegradable raw materials, and sustainable packaging solutions. Finally, corporate accountability is reinforced by the establishment of robust post-market surveillance systems and the capacity for rapid and effective product recall, ensuring continued protection of both consumers and the environment (Turkish Official Gazette, 2023).

10. Conclusion

The safe manufacture of cosmetic and cleaning products is achieved through the integration of GMP-based operational excellence, comprehensive safety assessment, and transparent risk communication. In Türkiye, the alignment of the Cosmetic Products Regulation with European Union standards provides a structured and systematic framework, particularly through the implementation of the Product Information File (PIF) and the clearly defined legal responsibilities of the Responsible Person.

Simultaneously, products bearing biocidal claims are subject to the stringent licensing and authorization requirements of the Biocidal Products Regulation, ensuring that efficacy, safety, and labeling accuracy are all addressed concurrently. Collectively, these regulatory pathways reflect a risk-based approach to market access grounded in scientific evidence and public health considerations.

Given the growing body of scientific evidence demonstrating the clinical burden of contact allergy and the respiratory risks associated with long-term exposure to cleaning agents, manufacturers should regard regulatory compliance not as an endpoint but as the minimum foundation for robust scientific risk management. Ultimately, an ethical and sustainable production paradigm requires proactive formulation design that minimizes latent and cumulative risks while ensuring that responsibilities are transparent to regulators, professionals, and consumers alike.

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