COSMETIC UTILIZATION AND ASSOCIATED ADVERSE EVENTS: PREVALENCE AND RISK FACTORS ANALYSIS

Thesis Submitted for the Award of the Degree of

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in

Pharmacology

By

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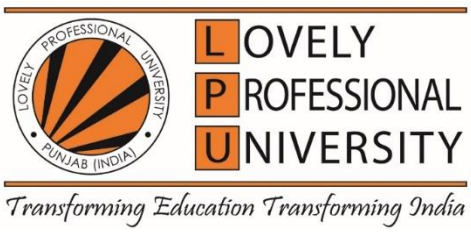

LOVELY PROFESSIONAL UNIVERSITY, PUNJAB
2024

DECLARATION

I, hereby declared that the presented work in the thesis entitled "Cosmetic utilization and associated adverse events: prevalence and risk factors analysis" in fulfilment of degree of **Doctor of Philosophy (Ph. D.)** is outcome of research work carried out by me under the supervision of Dr. Sanjeev Kumar Sahu, working as Professor, in the Pharmaceutical Chemistry at School of Pharmaceutical Sciences, Lovely Professional University, Punjab, India. In keeping with general practice of reporting scientific observations, due acknowledgements have been made whenever work described here has been based on findings of other investigator. This work has not been submitted in part or full to any other University or Institute for the award of any degree.

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CERTIFICATE

This is to certify that the work reported in the Ph. D. thesis entitled "Cosmetic utilization and associated adverse events: prevalence and risk factors analysis" submitted in fulfillment of the requirement for the award of degree of **Doctor of Philosophy (Ph.D.)** in the Pharmacology/School of Pharmaceutical Sciences, is a research work carried out by Sweta Kumari (Reg no. 41900772) is bonafide record of his/her original work carried out under my supervision and that no part of thesis has been submitted for any other degree, diploma or equivalent course.

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Name of supervisor: Dr. Sanjeev Kumar Sahu

Designation: Professor

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ABSTRACT

We aimed to explore patterns of cosmetic usage, along with associated adverse events, and to assess knowledge and attitudes towards cosmetics through community-based cross-sectional studies. Additionally, we sought to determine the prevalence of adverse events induced by cosmetics and identify associated risk factors through a systematic review and meta-analysis. A total of 400 respondents participated in the community-based cross-sectional study. More than half of the participants (54.7%) used 1–2 cosmetics per day, with nearly fifty percent (n = 49%) reportedly using them twice daily. The most commonly used cosmetics products were makeup and personal care products. A total of 132 users reported adverse events due to cosmetics. The prevalence of cosmetic-induced adverse events was found to be 33%. The most commonly reported adverse events were itching (frequency= 58), redness (frequency = 59), and pimples (frequency = 42). The majority of reported adverse events were related to skin care products 64 (46%), hair care 39 (28.1%), and personal care products 24 (17.3%). Furthermore, the systematic review and meta-analysis revealed highly prevalent adverse events associated with cosmetics globally, with a pooled prevalence of 41.1%. Subgroup analysis based on region revealed the highest prevalence in Africa (53.6%), followed by South America (38.0%), Asia (35.0%), and Europe (33.4%). Students exhibited a higher prevalence (51.1%) compared to the general population (36.8%). Several factors have been identified as contributors to the increased occurrence of cosmetic-induced adverse events. Habits such as the daily use of multiple cosmetics, frequent application, a personal or family history of allergies to specific medications and foods, female gender and younger age were more prone to both the use of cosmetics and subsequently exhibiting adverse reactions. Additionally, the act of mixing different cosmetic products and combining them with saliva or water was identified as a significant determinant contributing to the occurrence of cosmetic-induced adverse events. Additionally, the assessment of knowledge and attitudes regarding cosmetic usage among 380 participants in Punjab, India, showed only 22% of the participants had high knowledge and 41.7% had positive attitudes. Younger individuals, females, and those with higher education demonstrated higher

levels of knowledge and positive attitudes. This emphasizes the importance of targeted educational interventions to promote safer cosmetic practices and effectively mitigate adverse events. The prevalence of adverse events among cosmetics users was found to be high. Simultaneously, there was a lack of adequate knowledge of cosmetics and their adverse events, emphasizing the need to create awareness of the rational use of cosmetics among users. The findings advocate for cosmetovigilance, regulatory enhancements, and consumer awareness to ensure safer cosmetic usage.

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TABLE OF CONTENTS

LIST OF TABLE

LIST OF FIGURES

LIST OF ABBREVIATIONS

UV	Ultraviolet
SPF	Sun Protection Factor
AHAs	Alpha hydroxy acids
BHAs	Beta hydroxy acids
ACD	Allergic contact dermatitis
ADL	Activities of daily living
NM	Not mentioned
UK	United Kingdom
PCA	Pyrrolidone carboxylic acid.
ME-PPD	2-methoxymethyl-p-phenylenediamine
PTD	Para toluene-2,5-diamine
ACD	Acute contact dermatitis
NA	Not available
PPD	Para-phenylenediamine
AKI	Acute kidney injury
ETB	Ethiopian Birr
NPR	Nepalese Rupees
CVI	Content Validity Index
SPSS	Statistical Packages for Social Sciences
AOR	Adjusted odds ratio
CI	Confidence interval
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
JBI	Joanna Briggs Institute
MLE	Maximum Likelihood Estimator
Colipa	The European Cosmetic and Perfumery Association
SD	Standard Deviation

INR	Indian Rupee
AE	Adverse Events
NS	Not specified/not specified clearly;
F	Female
M	Male
U	Unclear
ETB	Ethiopian Birr
PCPs	Personal Care Products

CHAPTER - 1

1. Introduction

1.1 Definition

Cosmetics are products that are used to enhance or alter a person's appearance. They can be used on the skin, hair, nails, and other areas of the body. Basically, cosmetics are obtained from natural sources, or they are synthetic (1). Some common types of cosmetics include makeup, skincare products, hair care products, and fragrances. Makeup products can include foundation, lipstick, eyeliner, mascara, and eyeshadow, among others. It is important to note that some cosmetics may contain ingredients that can be harmful to some people, such as those with sensitive skin or allergies. It is always a good idea to read the ingredients list and do a patch test before using a new cosmetic product (2).

Cosmetics refer to a broad category of products that are used to enhance or alter the appearance of the face and body. These products are primarily designed for personal grooming and aesthetic purposes. Cosmetics include a wide range of items, each serving a specific function in the realm of beauty and personal care (1).

1.2 History of cosmetics

In the ancient world, cosmetics played a pivotal role in shaping cultural aesthetics, religious practices, and societal norms. Ancient Egypt stands out with its renowned use of cosmetics, notably kohl, which held both cosmetic and protective significance, believed to ward off evil spirits and protect against the sun (3). Meanwhile, in ancient Greece, cosmetic practices were influenced by ideals of pale skin, leading to the use of white lead and chalk (4). The application of rouge and other pigments was associated with social status, highlighting notions of wealth and refinement. The ancient Romans adopted and adapted Greek cosmetic practices, emphasizing personal grooming and skincare (5). Both men and women used various creams and powders, contributing to hygiene and societal expectations of cleanliness. In ancient China, cosmetics were deeply rooted in Confucian ideals, emphasizing balance between inner virtue and outward appearance. Chinese beauty practices included powders made from natural ingredients like rice flour and face paints, reflecting cultural values (5). Mesopotamian civilizations, including Sumer and Babylon, embraced cosmetics

for skincare and adornment (5). Eye makeup, akin to kohl, was popular, and henna was used for hair coloring. Across these civilizations, cosmetics were not merely about enhancing beauty but held symbolic and religious significance. They were integrated into rituals and ceremonies, connecting personal adornment to broader cultural and spiritual contexts (5).

In ancient India, cosmetics played a multifaceted role, intertwining beauty practices with cultural, spiritual, and medicinal significance. Dating back thousands of years, cosmetic traditions in ancient India were deeply rooted in the principles of Ayurveda, emphasizing the use of natural ingredients for holistic well-being (6). Cosmetic practices, collectively known as "Sringara," extended beyond physical adornment, encompassing spiritual and ritualistic dimensions. The application of cosmetics, such as bindi and kumkum, held cultural significance, with the bindi symbolizing the third eye and kumkum serving as a mark of auspiciousness, particularly for married women (7). Ayurvedic beauty rituals emphasize the use of herbal pastes, oils, and powders. Ingredients like sandalwood, turmeric, amla, and neem were incorporated into skincare and haircare routines, not just for their cosmetic benefits but also for their medicinal properties.

Cosmetic practices in ancient India were interwoven with spiritual beliefs, turning the application of cosmetics into sacred rituals. Specific cosmetic elements were employed during ceremonies to connect with deities, emphasizing the holistic connection between physical appearance and spiritual well-being. Traditional attire and adornments complemented cosmetic practices, with intricate hairstyles, fragrant oils, and jewelry enhancing the overall aesthetic. The diversity of cosmetic rituals across regions reflected the rich cultural tapestry of ancient India, with unique customs and traditions influencing beauty practices (5).

1.3 Types of cosmetics

Different types of cosmetics are presented in Figure 1.

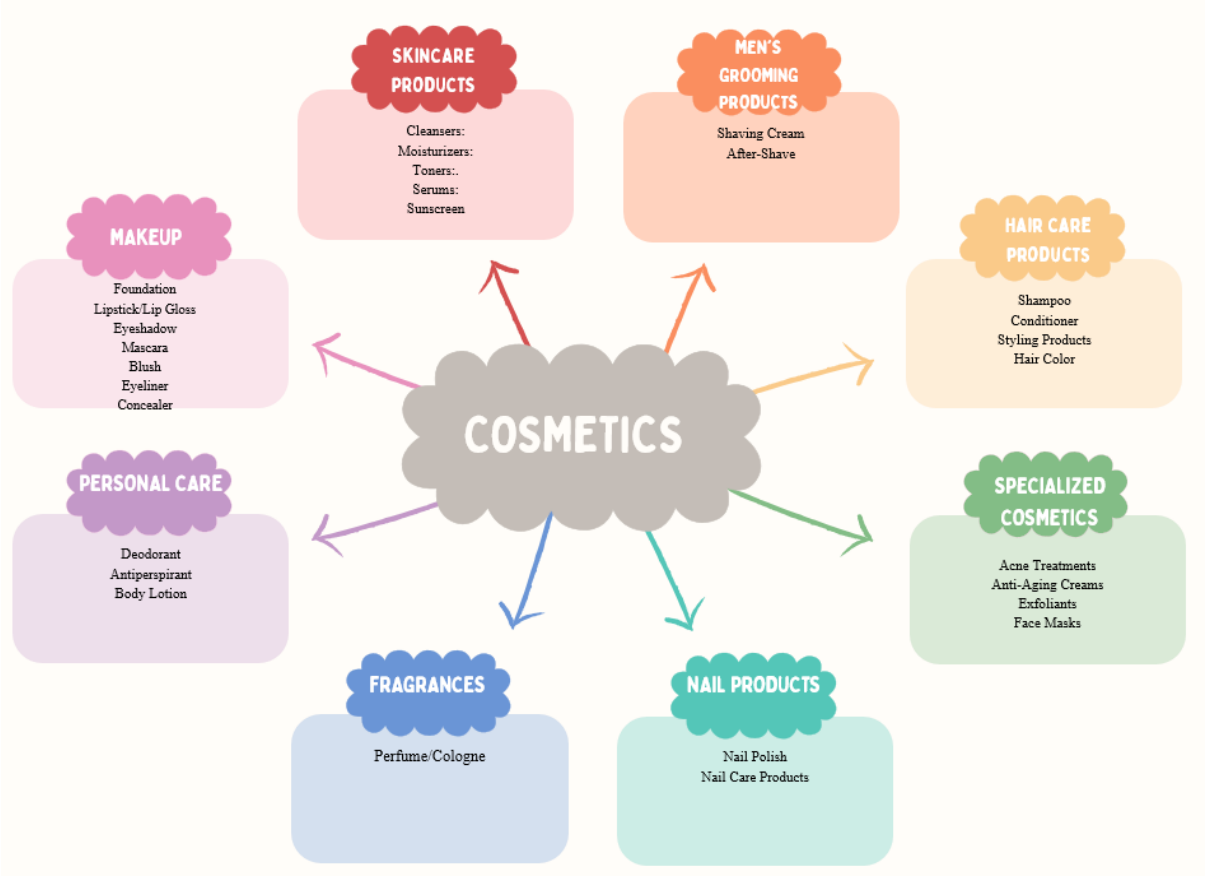

Figure 1. Types of cosmetics

1.3.1 Skincare Products

Skincare products encompass a wide range of formulations designed to cleanse, nourish, protect, and improve the health and appearance of the skin. These products cater to various skin types and concerns. Here are some common types of skincare products:

1.3.1.1 Cleansers

Cleansers play a vital role in skincare by effectively removing dirt, oil, makeup, and other impurities from the skin's surface. The primary purpose of cleansers is to maintain skin hygiene, unclog pores, and prepare the skin for the application of subsequent skincare products. Regular cleansing helps prevent breakouts, reduces the risk of skin infections, and promotes a clean and refreshed complexion. Different types of cleansers cater to various skin types and concerns, offering a personalized approach to skincare routines (8).

1.3.1.2 Moisturizers

Moisturizers are essential skincare products designed to hydrate and nourish the skin, helping to maintain its natural moisture balance. The primary purpose of moisturizers is to prevent dehydration, improve skin texture, and create a protective barrier that locks in moisture. By replenishing the skin's hydration levels, moisturizers contribute to a smoother, softer, and more complexion. Additionally, moisturizers may contain various active ingredients targeting specific concerns such as aging, sensitivity, or uneven skin tone (9).

1.3.1.3 Toners

Toners have evolved significantly from their traditional role as astringents to become versatile skincare essentials. Modern toners go beyond cleansing, offering hydration, restoring pH balance, and preparing the skin for subsequent skincare products. Hydrating toners, enriched with ingredients like hyaluronic acid, leave the skin refreshed. They now incorporate diverse ingredients such as antioxidants and vitamins, providing anti-aging and soothing benefits. Toners play a crucial role in the clean beauty movement, with many brands focusing on sustainability. The evolution of toners showcases the dynamic nature of skincare, emphasizing their adaptability and efficacy in contemporary skincare routines (10).

1.3.1.4 Serums

Serums are potent skincare formulations designed to address specific skin concerns and deliver concentrated active ingredients. These lightweight and highly absorbent

products have become essential in skincare routines. Serums cater to diverse needs, offering solutions for issues like hydration, anti-aging, brightening, and more. Their liquid or gel-like consistency allows for deep penetration into the skin, making them effective in targeting specific concerns. Serums are typically applied after cleansing and before moisturizing, providing a targeted boost to a skincare routine. They exemplify a focused and intensive approach to skincare, contributing to the overall health and appearance of the skin (11).

1.3.1.5 Sunscreen

Sunscreen is a crucial skincare product designed to protect the skin from the harmful effects of ultraviolet (UV) rays emitted by the sun. It acts as a barrier, preventing sunburn, premature aging, and reducing the risk of skin cancer. Sunscreens come in various forms, including lotions, creams, and sprays, with different Sun Protection Factor (SPF) levels. They work by absorbing or reflecting UV radiation, safeguarding the skin from damage caused by prolonged sun exposure. Incorporating sunscreen into a daily skincare routine is essential for maintaining skin health and preventing sun-induced skin issues (12).

1.3.2 Makeup cosmetics

Makeup cosmetics encompass a diverse range of products designed to enhance and beautify facial features. From creating a flawless complexion to adding color and definition to eyes, lips, and cheeks, makeup products cater to various preferences and styles. Key categories include foundation for skin coverage, eyeshadows and eyeliners for eye definition, lipsticks and lip glosses for lip color, blush for a rosy complexion, and more. These products are available in a variety of formulations, from liquids and creams to powders and pencils, allowing users to achieve different finishes and effects. Makeup artists and enthusiasts utilize an array of techniques, such as contouring, highlighting, and blending, to create desired looks, whether natural, glamorous, or artistic (13).

Makeup care products, including makeup removers, setting sprays, and skincare items, are essential for proper application and removal, contributing to healthy skin maintenance. As trends evolve, the beauty industry introduces new formulations,

color palettes, and innovative products to meet diverse preferences and keep up with the ever-changing landscape of beauty and fashion. In essence, makeup cosmetics are powerful tools that empower individuals to express themselves creatively, boost confidence, and celebrate their unique features, contributing to the dynamic and continually evolving world of beauty (14).

1.3.2.1 Foundation: Foundation is a crucial makeup product designed to create a smooth and even skin tone. Available in various formulations such as liquid, cream, powder, and stick, it conceals imperfections and provides a base for additional makeup. Foundations cater to different skin types, offering options for a natural finish, full coverage, or a matte look. The evolution of foundation includes inclusive shade ranges and formulations with skincare benefits (15).

1.3.2.2 Lipsticks: Lipsticks are iconic cosmetic products known for adding color and definition to the lips. Available in a variety of finishes, including matte, glossy, satin, and liquid, lipsticks cater to diverse preferences. They come in an array of shades, allowing individuals to express their style and enhance their lip shape. Lipsticks are essential for completing makeup looks, ranging from subtle to bold and dramatic (16).

1.3.2.3 Mascara: Mascara is a key eye makeup product designed to enhance eyelashes by adding volume, length, and definition. This cosmetic essential comes in various types, including volumizing, lengthening, and waterproof formulas. Mascara opens up the eyes, creating a more awake and polished appearance. It is a go-to product for accentuating eyelashes and achieving a wide range of eye makeup looks, from natural to dramatic (17).

1.3.2.4 Eyeshadow: Eyeshadow is a versatile cosmetic product applied to the eyelids to enhance and define the eyes. Available in various forms such as powder, cream, and liquid, eyeshadows come in a wide array of colors and finishes. They allow for creative expression, enabling the creation of diverse eye makeup looks, from subtle and natural to bold and dramatic. Eyeshadows are essential for adding depth, dimension, and a pop of color to the eyes (18).

1.3.2.5 Blush: Blush is a makeup product applied to the cheeks to add a healthy and rosy flush to the complexion. Available in powder, cream, and liquid formulations,

blush enhances the natural contours of the face, creating a youthful and radiant appearance. Blush comes in a variety of shades to suit different skin tones and preferences. It is a key component of makeup routines, contributing to a polished and vibrant overall look (19).

1.3.2.6 Eyeliners: Eyeliners are cosmetic products used to define and accentuate the eyes. Available in pencil, liquid, gel, and felt-tip forms, eyeliners allow for precise application, enabling the creation of various eye looks. They can be applied to the upper and lower lash lines to add definition, create drama, or achieve a winged effect. Eyeliners are versatile tools for enhancing eye shape and intensifying overall eye makeup (20).

1.3.2.7 Concealer: Concealer is a makeup product designed to camouflage imperfections, such as blemishes, dark circles, and uneven skin tone. Available in liquid, cream, stick, and color-correcting formulations, concealers provide targeted coverage for specific areas of concern. They contribute to achieving a flawless complexion by brightening and evening out the skin tone. Concealers are an essential component of makeup routines, offering a quick and effective way to achieve a polished look (21).

1.4 Hair care products

Hair care products encompass a range of formulations designed to cleanse, condition, style, and enhance the appearance of the hair. Key products include shampoo, which cleanses the scalp and removes impurities; conditioner, which moisturizes and improves hair texture; styling products for shaping and holding hairstyles; and hair color for aesthetic transformations. These products cater to diverse hair needs, offering solutions for cleansing, hydration, styling, and color customization. Together, they contribute to overall hair health, manageability, and the ability to achieve a variety of desired looks (22).

1.4.1 Shampoo: Shampoo is a hair care product formulated to cleanse the scalp and hair by removing dirt, oil, and product residue. It comes in various types, including moisturizing, volumizing, and clarifying, catering to different hair needs. Shampoo

helps maintain scalp health, promotes cleanliness, and prepares the hair for subsequent conditioning and styling products (23).

1.4.2 Conditioner: Conditioner is a hair care product applied after shampooing to moisturize, detangle, and improve the overall texture of the hair. It comes in various formulations, such as moisturizing, volumizing, and deep conditioning. Conditioners work to replenish moisture, smooth the hair cuticle, and enhance manageability, leaving the hair soft, shiny, and more resilient (23).

1.4.3 Styling Products: Styling products encompass a wide range of formulations, including gels, mousses, serums, and sprays, designed to shape, hold, and enhance hairstyles. These products provide versatility in styling, allowing individuals to achieve specific looks such as volume, curls, or sleek finishes. Styling products also offer heat protection and control frizz, contributing to the overall aesthetics of the hair (23).

1.4.4 Hair Color: Hair color products are used to alter the natural color of the hair for aesthetic purposes. They come in various forms, including permanent, semi-permanent, and temporary dyes. Hair color allows individuals to experiment with different shades, cover grays, or achieve a bold and vibrant look. Advanced formulations often include conditioning agents to minimize damage and enhance the vibrancy of the color (23).

1.5 Fragrance

Fragrance cosmetics represent an enchanting intersection of beauty and scent, offering a sensory experience that goes beyond visual aesthetics. Comprising perfumes, scented lotions, and other fragranced products, these cosmetics aim to enhance personal grooming by incorporating captivating and harmonious scents. Fragrance cosmetics play a dual role, not only contributing to an individual's overall appearance but also leaving a lasting olfactory impression. The artistry of crafting these scents involves the careful blending of aromatic compounds to create unique, expressive, and memorable fragrances. As an integral part of the beauty industry, fragrance cosmetics add an extra layer of sophistication and allure to daily routines, providing

individuals with an opportunity to make a distinctive and memorable statement through the power of scent (24).

1.6 Perfume and cologne

Perfume and cologne are fragrant compositions crafted to enhance personal grooming and create a lasting olfactory impression. These aromatic products, commonly known as scents, are carefully formulated by blending various aromatic compounds to achieve a distinctive and pleasing aroma. Perfumes typically contain a higher concentration of fragrance oils, resulting in a more potent and long-lasting scent, while colognes feature a lighter concentration, making them suitable for everyday wear. Both perfume and cologne serve as a means of self-expression, allowing individuals to convey their personality, mood, or style through the captivating medium of fragrance. These products are essential elements of the beauty industry, adding a sensory layer to personal care routines and contributing to an individual's overall aura (25).

1.7 Nail cosmetics

Nail cosmetics encompass a variety of products designed to enhance the appearance of the nails. Nail polish, the most iconic of these products, comes in a myriad of colors and finishes, allowing for creative expression and personal style. Nail care items, such as base coats and topcoats, contribute to the longevity of a manicure. Additionally, nail art tools and accessories provide further customization, allowing individuals to experiment with unique designs and trends. Nail cosmetics play a prominent role in the beauty industry, offering a versatile and expressive way to groom and adorn the nails, completing the overall aesthetic of an individual's appearance (26).

1.7.1 Nail Polish: Nail polish is a cosmetic product applied to the nails to add color and aesthetic appeal. Available in a vast array of colors, finishes, and formulations, it allows for creative expression and personal style. Nail polish typically consists of a base coat, color layer, and topcoat, contributing to a polished and long-lasting manicure. It is a staple in the beauty industry, offering a versatile way to enhance the nails and complete one's overall look (27).

1.7.2 Nail Care Products: Nail care products comprise a range of items designed to maintain the health and appearance of the nails. This category includes base coats, which provide a protective layer; topcoats, offering gloss and extended wear; cuticle oils and creams for hydration; and nail strengtheners to promote resilience. Nail care is essential for preventing damage, promoting growth, and ensuring a well-groomed appearance. These products contribute to overall nail health and enhance the longevity of manicures (28).

1.8 Personal care cosmetics

Personal care cosmetics encompass a wide range of products designed to enhance personal hygiene, grooming, and appearance. These products are an integral part of daily routines for many individuals, contributing to their overall well-being and self-esteem. Consumers often choose personal care cosmetics based on individual preferences, skin type, and desired effects. The industry has seen a surge in demand for natural and organic products, with an increased focus on sustainability and cruelty-free options. Innovation in formulations, such as the inclusion of advanced skincare ingredients or eco-friendly packaging, is also a notable trend in the personal care cosmetics sector (29).

1.8.1 Deodorant: Deodorants are personal care products designed to prevent or mask body odor caused by bacterial breakdown of perspiration. They often contain antimicrobial agents to inhibit bacterial growth, and some may also include fragrances for a pleasant scent. Deodorants are commonly applied to the underarms and come in various forms, including sticks, roll-ons, sprays, and creams. Some formulations are specifically designed to provide long-lasting protection or cater to sensitive skin (30).

1.8.2 Antiperspirant: Antiperspirants are similar to deodorants but go a step further by reducing or temporarily blocking the production of sweat. They typically contain aluminum-based compounds that form a temporary plug within the sweat ducts, reducing the amount of sweat that reaches the skin's surface. Antiperspirants are especially popular for those looking to manage excessive sweating, particularly in areas like the underarms. Like deodorants, antiperspirants also come in various forms to suit individual preferences (30).

1.8.3 Body lotion: Body lotions are skincare products designed to hydrate and nourish the skin, promoting a smooth and supple texture. These formulations often include moisturizing agents such as oils, butters, and humectants that help retain the skin's moisture. Body lotions are commonly used to address dry skin, especially after bathing or exposure to harsh environmental conditions. They come in a variety of scents and formulations, catering to different skin types and preferences. Some body lotions may also include additional ingredients like vitamins, antioxidants, or anti-aging compounds for added skincare benefits (31).

1.9 Specialized cosmetics

Specialized cosmetics refer to a category of beauty and skincare products that are formulated to address specific concerns or provide targeted solutions for various skin and beauty needs. Unlike general-use cosmetics, specialized products are designed with a focus on particular skin conditions, concerns, or desired effects. Specialized cosmetics offer consumers a tailored approach to their beauty and skincare needs, allowing them to address specific concerns or achieve desired effects. The continual innovation in the cosmetics industry ensures that individuals have access to a diverse range of specialized products catering to various preferences and requirements (32).

1.9.1 Acne Treatments: Acne treatments are skincare products specifically formulated to address various types of acne, including pimples, blackheads, and whiteheads. These products often contain active ingredients such as benzoyl peroxide, salicylic acid, or alpha hydroxy acids (AHAs) to target acne-causing bacteria, unclog pores, and reduce inflammation. Some acne treatments also include soothing agents to minimize irritation and prevent further breakouts. They come in various forms, including cleansers, spot treatments, and leave-on formulations (33).

1.9.2 Anti-Aging Creams: Anti-aging creams are skincare products designed to combat the signs of aging, such as fine lines, wrinkles, and loss of skin elasticity. These creams often contain ingredients like retinol, hyaluronic acid, peptides, and antioxidants. Retinol promotes cell turnover and collagen production, while hyaluronic acid hydrates the skin. Peptides help improve skin firmness, and antioxidants protect against environmental damage. Anti-aging creams aim to reduce

the appearance of wrinkles, improve skin texture, and promote a more youthful complexion (34).

1.9.3 Exfoliants: Exfoliants are skincare products that help remove dead skin cells from the skin's surface, promoting a smoother and more radiant complexion. There are two main types of exfoliants: physical exfoliants, which contain small particles to manually scrub away dead skin, and chemical exfoliants, which use ingredients like alpha and beta hydroxy acids (AHAs and BHAs) to dissolve dead skin cells. Regular exfoliation can improve skin texture, unclog pores, and enhance the absorption of other skincare products (35).

1.9.4 Face Masks: Face masks are skincare treatments that offer various benefits depending on their formulations. They come in different types, including clay masks, sheet masks, and gel masks. Clay masks are known for their ability to absorb excess oil and unclog pores, making them suitable for oily and acne-prone skin. Sheet masks are pre-soaked fabric masks that deliver concentrated ingredients to the skin, providing hydration and addressing specific concerns. Gel masks are often soothing and hydrating, making them suitable for sensitive or dry skin. Face masks can offer a quick and targeted boost to the skin, addressing specific needs such as hydration, brightening, or purifying (36).

1.10 Men’s Grooming Products:

Men's grooming products have experienced a significant surge in popularity, reflecting a growing trend of men taking a proactive approach to personal care and grooming. This category encompasses a diverse range of products tailored to meet the specific needs of men’s skin, hair, and overall grooming routines (37).

1.10.1 Shaving Cream: Shaving cream is a crucial component of the shaving routine, providing a lubricated surface for the razor to glide smoothly across the skin. Its primary purpose is to soften the hair, making it easier to cut, and to create a protective barrier between the razor and the skin. Shaving creams come in various formulations, including traditional creams, gels, and foams, each catering to different preferences. Many modern shaving creams also incorporate moisturizing agents and soothing ingredients to prevent irritation and leave the skin feeling refreshed after shaving.

Some formulations may be enriched with botanical extracts or essential oils for added skin benefits and a pleasant fragrance. Using a quality shaving cream contributes to a comfortable and effective shaving experience while minimizing the risk of nicks, cuts, and razor burn (38).

1.10.2 After Shave: After shave is a skincare product applied to the skin after shaving to soothe and refresh. It typically comes in liquid or balm form and contains ingredients that help alleviate irritation, close pores, and provide a cooling sensation. Common ingredients in after shave formulations include astringents, such as witch hazel or alcohol, which can help tighten the skin and reduce inflammation. Additionally, after shaves may include moisturizing agents like aloe vera or glycerin to hydrate the skin and prevent dryness. Some after shaves also feature antiseptic properties to help prevent infection in case of any minor cuts or nicks during shaving. Beyond its practical benefits, after-shave often imparts a subtle fragrance, adding a pleasant finishing touch to the shaving ritual. Regular use of after shave contributes to a smoother post-shave experience, leaving the skin feeling invigorated and well-nourished (38).

1.11 Awareness of cosmetics products

Cosmetics products encompass a vast array of beauty and skincare items designed to enhance, highlight, and care for various aspects of the body. A comprehensive understanding of cosmetics products involves knowledge of ingredients, formulations, application techniques, and the broader cultural and industry trends that shape the beauty landscape (39). In this exploration, we delve into the key facets of cosmetics product knowledge, emphasizing its importance in making informed choices and fostering a holistic approach to personal care.

1.11.1 Ingredient Awareness:

Knowledge of cosmetics begins with an understanding of ingredients. Consumers are increasingly conscious of what goes into their beauty products, scrutinizing labels for ingredients like hyaluronic acid for hydration, retinol for anti-aging, or natural extracts for specific skin benefits. This awareness enables individuals to make choices aligned with their skin concerns and preferences (40).

1.11.2 Formulations and Efficacy:

Formulations play a pivotal role in the effectiveness of cosmetics products. A knowledgeable consumer comprehends the synergy between different ingredients and their intended effects. This awareness empowers individuals to select products tailored to address specific skin needs, from moisturizing and brightening to treating acne or reducing fine lines (41).

1.11.3 Application Techniques:

Understanding the correct application techniques enhances the efficacy of cosmetics. Whether it's the proper way to layer skincare products or the precision required for makeup application, knowledge of application techniques ensures that individuals achieve optimal results and maximize the benefits of their chosen products.

1.11.4 Skin Types and Personalized Regimens:

A nuanced understanding of skin types is fundamental to crafting personalized skincare regimens. Different skin types require specific products and treatments, and knowledge in this area helps consumers curate routines that cater to their unique needs, promoting overall skin health (42).

1.11.5 Cultural Influences on Beauty Preferences:

Cosmetics knowledge extends beyond individual preferences to an awareness of cultural influences on beauty standards. Recognizing diverse beauty ideals and global trends enables consumers to appreciate and incorporate a variety of beauty practices, fostering a more inclusive approach to personal care (43).

1.11.6 Ethical Considerations and Sustainability:

An informed consumer considers ethical dimensions in cosmetics choices. Awareness of cruelty-free practices, eco-friendly packaging, and sustainable sourcing contributes to conscious decision-making, aligning beauty choices with personal values and global environmental concerns (44).

1.11.7 Evolving Industry Trends:

Staying abreast of industry trends is integral to cosmetics knowledge. From emerging skincare ingredients to the latest makeup techniques, awareness of trends allows consumers to explore new products and techniques while remaining informed about the dynamic beauty landscape (45).

1.11.8 Health and Safety Awareness:

Health and safety awareness in the cosmetics industry signifies a growing consumer consciousness regarding the impact of beauty products on personal well-being. Key aspects include scrutinizing ingredients for allergens and harmful chemicals, practicing safe application techniques, and adopting a proactive approach to allergen sensitivity through patch testing. Consumers prioritize products with regulatory compliance and certifications, seeking expert recommendations and valuing ingredient transparency. The clean beauty movement, marked by a preference for safer, more transparent practices, reflects a broader commitment to skin health, shaping the trajectory of the cosmetics landscape towards a more informed and health-conscious future (46, 47).

1.12 Adverse events and classification of adverse events

The terms "adverse event" is frequently used interchangeably with "adverse drug reaction," but they actually refer to distinct concepts. According to the World Health Organization, an adverse event refers to any medical occurrence that happens in association with the use of a medicinal product, but it is not necessarily caused by it (48).

Common Terminology Criteria for Adverse Events (CTCAE) classified adverse events based on severity, ranging from Grade 1 to Grade 5. Each grade is accompanied by specific clinical descriptions that outline the severity of the AE based on the following guidelines (49):

- Grade 1: Mild; the individual is asymptomatic or experiences only mild symptoms. Clinical or diagnostic observations are present, but no intervention is indicated.

- Grade 2: Moderate; minimal local or non-invasive intervention is required. The event limits age-appropriate instrumental activities of daily living (ADL).
- Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or an extension of hospitalization is required. The event is disabling and limits self-care ADL.
- Grade 4: Life-threatening consequences; urgent intervention is necessary.
- Grade 5: Death related to the adverse event.

This grading system aids in the assessment and management of AEs, ensuring appropriate responses based on severity.

1.13 Adverse effects of cosmetics

While cosmetics are designed to enhance beauty and personal care, it's crucial to be aware of potential adverse effects that certain products may pose (50). Here's a detailed exploration of common adverse effects associated with cosmetics (50-60):

1.13.1 Skin Irritation and Allergies:

Causes: Fragrances, preservatives (e.g., parabens), and colorants.

Effects: Redness, itching, swelling, and allergic reactions.

1.13.2 Contact Dermatitis:

Causes: Allergens or irritants present in cosmetics, such as certain fragrances, preservatives, and dyes.

Effects: Inflammation, redness, itching, and sometimes blistering in the affected area.

1.13.3 Acne and Pore Congestion:

Causes: Comedogenic ingredients, heavy or oil-based formulations.

Effects: Development of blackheads, whiteheads, and acne lesions.

1.13.4 Eye Irritation:

Causes: Eye makeup products, particularly eyeliners and mascaras.

Effects: Redness, watery eyes, swelling, and allergic reactions.

1.13.5 Photo allergic Reactions:

Causes: Photosensitizing ingredients in cosmetics, like certain fragrances or botanical extracts.

Effects: Redness, itching, blistering, and rash upon exposure to sunlight.

1.13.6 Hormonal Disruption:

Causes: Endocrine-disrupting chemicals, such as parabens and phthalates.

Effects: Potential interference with hormonal balance, contributing to reproductive health issues.

1.13.7 Heavy Metal Contamination:

Causes: Contaminated cosmetics, especially certain imported products.

Effects: Long-term exposure to heavy metals like lead, mercury, or arsenic can lead to serious health concerns.

1.13.8 Respiratory Issues:

Causes: Inhalation of airborne particles from powders, sprays, or aerosolized products.

Effects: Respiratory discomfort, especially in individuals with pre-existing respiratory conditions.

1.13.9 Skin Sensitization:

Causes: Prolonged use of certain cosmetic ingredients.

Effects: Sensitization, making the skin more prone to reactions over time, contributing to chronic skin issues.

1.13.10 Microbial Contamination:

Causes: Contaminated or expired cosmetics.

Effects: Infections when applied to the skin or eyes, emphasizing the importance of proper storage and hygiene practices.

1.13.11 Allergic Contact Dermatitis:

Causes: Allergens like fragrances, preservatives, and certain metals (e.g., nickel).

Effects: Delayed hypersensitivity reaction leading to skin inflammation, redness, and itching.

1.13.12 Skin Discoloration:

Causes: Some cosmetics may contain ingredients that lead to hyperpigmentation or hypopigmentation.

Effects: Uneven skin tone or discoloration, particularly with prolonged or excessive use.

1.13.13 Paradoxical Effects:

Causes: Unexpected reactions to certain ingredients that might have opposite effects.

Effects: For example, a moisturizing product may unexpectedly cause dryness or irritation in some individuals.

It's important for consumers to be proactive in understanding ingredient lists, performing patch tests, and monitoring their individual reactions to different products. Any persistent adverse effects should prompt discontinuation of use and consultation with a healthcare professional. Regularly checking for product recalls and staying informed about industry practices can contribute to a safer cosmetic experience. Additionally, choosing products based on individual skin types and concerns plays a vital role in mitigating potential risks associated with cosmetics.

1.14 Risk factor for adverse effects

Various risk factors contribute to the occurrence of adverse effects associated with cosmetics. These factors can result from the formulation of the products, individual characteristics, or external influences. Here are key risk factors for cosmetics adverse effects (50-52):

1.14.1 Ingredient Sensitivity:

Risk Factor: Individuals may have sensitivities or allergies to specific cosmetic ingredients, such as fragrances, preservatives, or certain dyes (61).

Impact: Sensitivity can lead to skin irritation, redness, itching, or allergic reactions upon exposure to the allergenic components (61).

1.14.2 Skin Type and Conditions:

Risk Factor: Different skin types (oily, dry, sensitive) and pre-existing skin conditions influence how products interact with the skin (62).

Impact: Individuals with sensitive skin, for example, may be more prone to adverse reactions, while those with oily skin may be susceptible to pore congestion and acne (62, 63).

1.14.3 Product Formulation:

Risk Factor: The formulation of cosmetic products, including the concentration and combination of ingredients, can impact their safety (46).

Impact: Products with harsh or comedogenic ingredients may contribute to adverse effects, including irritation, redness, or acne (64).

1.14.4 Incorrect Product Usage:

Risk Factor: Misuse or incorrect application of cosmetics, such as using expired products, applying excessive amounts, or not following recommended usage guidelines.

Impact: Incorrect usage can lead to adverse effects, including microbial contamination, skin sensitization, and compromised product efficacy (65, 66).

1.14.5 Cumulative Exposure:

Risk Factor: Prolonged or frequent use of certain products may increase the risk of adverse reactions due to cumulative exposure to specific ingredients (58).

Impact: Sensitization, where the skin becomes more reactive over time, is a potential consequence of cumulative exposure to certain cosmetic components (67).

1.14.6 Age and Hormonal Changes:

Risk Factor: Age-related changes and hormonal fluctuations can affect skin sensitivity and responsiveness to cosmetic products (68, 69).

Impact: Adolescents, pregnant individuals, and those going through hormonal changes may be more susceptible to adverse effects (70, 71).

1.14.7 Environmental Factors:

Risk Factor: Exposure to environmental elements, such as pollution, UV radiation, and climate conditions, can interact with cosmetic products on the skin (72).

Impact: Environmental factors can exacerbate adverse effects, especially if products do not provide adequate protection or if individuals have heightened skin sensitivity (73).

1.14.8 Microbial Contamination:

Risk Factor: Improper storage, hygiene practices, or the use of contaminated applicators can introduce harmful bacteria into cosmetic products (74).

Impact: Microbial contamination can lead to infections, particularly in products applied to the skin or around the eyes (74).

1.14.9 Quality and Safety Standards:

Risk Factor: Variations in product quality, adherence to safety standards, and regulatory compliance influence the safety of cosmetic formulations (75, 76).

Impact: Inadequate quality and safety measures can result in harmful products reaching consumers, leading to adverse health effects and fading trust in cosmetic brands (75, 76)

1.15 Need for comprehensive analysis of cosmetic induced adverse events: systematic review and meta-analysis

Global data on cosmetic-induced adverse events suggest relatively low reporting rates; however, these figures may be underestimated due to factors like self-diagnosis, self-treatment, and a lack of medical consultation, especially for mild to moderate reactions (56, 77). This under-reporting raises concerns about the true extent of adverse events related to cosmetic use. As a result, it is essential to thoroughly assess and evaluate the prevalence and risk factors associated with cosmetic-induced adverse events through an in-depth analysis of existing studies.

A systematic review provides a methodical approach to gathering, assessing, and synthesizing relevant research on a specific question. By following a pre-defined protocol, it reduces bias and offers a comprehensive summary of the available evidence. This process involves clearly defining the research question, setting inclusion criteria, conducting extensive literature searches, and critically evaluating study quality. Alongside this, a meta-analysis is often employed, which is a statistical method that combines results from multiple studies to calculate an overall effect size (78-80). This enhances the reliability and generalizability of the findings, making it an invaluable tool for identifying trends and providing a clearer understanding of the prevalence of cosmetic-induced adverse events.

CHAPTER – 2

2. Review of literature

2.1 Lip cosmetics and adverse effects

2.1.1 Allergic contact dermatitis

Allergic contact dermatitis (ACD) is an inflammatory skin condition triggered by a type 4 hypersensitivity reaction. The diagnosis relies on a comprehensive evaluation, including a detailed medical history, a thorough physical examination, and the gold standard, which is patch testing, for confirming the diagnosis of ACD. In this study patch test was negative in one study in which a 29-year-old female developed hyperpigmentation on lips associated with inflammation of the angles of the mouth after occasional use of lipstick (81). The exact cause of her hyperpigmentation was not known. The patient belongs to the high-risk population of melanosis and her medical history was suggestive for chemical irritation than allergic response. It was thought to be phototoxic reaction and mechanical irritation. Non allergic cause of pigmented textile contact dermatitis was reported in previous study (81). Hyperpigmentation is also reported to happen after phototoxic response and mechanical irritation. We found a case of contact urticaria in a 3-year-old patient, triggered by lip plumper, after the child's mother kissed him on the cheek (82). Immediately after applying a small volume of the product to the cheek of the mother, a tingling sensation and urticarial plaque developed. Lip plumper are cosmetic products used to increase lip volume by vasodilation secondary to either irritant contact dermatitis or non-immunologic contact urticaria. Lip plumber consisted of Capsicum frutescens and benzyl nicotinate. Capsicum has irritating and urticariant properties, and benzyl nicotinate, which has immediate vasodilatory effects. These ingredients were suspected to be the cause of contact urticaria. In another study conducted by Prakash et al., contact stomatitis was observed in a 17-year-old female following the use of lip balm (83). The specific allergen could not be definitively identified due to the patient’s limited socioeconomic status. The diagnosis was established primarily based on the patient's medical history and the results of provocative testing. The commonly suspected chemicals responsible for causing ACD are discussed below in Table 1.

Table 1. Suspected chemicals responsible for causing ACD

Reference / Year	Country	Age/Sex	Type of lip cosmetics formulation	Causative Ingredients	Patch test	Clinical Outcome
Cronin et al. 1980 (84)	England	58 / Female	Lipstick	Propyl gallate	Propyl gallate (2% pet.) +, Own lipsticks +	Resolution of lesions
Serra-baldrich et al. 1995 (85)	Spain	30/ Female 31/ Female 35/ Female 32/ Female 39/ Female 44/ Male	Lipstick Lipstick Lipstick Lipstick Lipstick Lipstick	Propyl gallate	Octyl gallate ++ Dodecyl gallate ++ Octyl gallate ++ Dodecyl gallate ++ Propyl gallate ++ Octyl gallate ++	NM
Ozkaya et al. 2007 (86)	Turkey	29 / Female	Lipstick	Propyl gallate	Own lipstick ++, Propyl gallate (0.5% pet.) +++	Resolution of lesions
Nandkishor et al. 1994 (87)	India	23/ Female	Lipstick	Propyl gallate, Octyl gallate	Positive to propyl gallate (1% pet.), Octyl	NM

					gallate (0.25% pet.), and own lipstick	
Wilson et al. 1989 (88)	USA	58 / Female	Lip balm	Propyl gallate	Positive to propyl gallate (2% pet.) and own lip balm	Resolution of the lesions
Anderson et al. 1984 (89)	Denmark	29/ Female	Lipstick	Castor oil	Own lipstick ++, Castor oil ++, Ricinoleic acid +++	Resolution of the lesions
Sánchez-Herrero et al. 2018 (90)	Spain	13 / Male	Lip balm	Castor oil	Castor oil (20% pet.) ++, Own lip balm ++	Resolution of the lesions
Suhkho Sai 1983 (91)	Japan	22/ Female	Lipstick and lip creams	Ricinolic acid	Ricinoleic acid (30% pet.) ++, Castor oil ++, Own lip care products ++	NM
Tan et al. 1997 (92)	UK	29 / Female	Lipstick	Ricinoleic acid, lanolin, Oleyl alcohol,	Own lipstick ++, Oleyl alcohol (10% pet.) +++, Ricinoleic	NM

					acid (0.1, 1.0, 10% pet.) ++	
Junko et al. 2003 (93)	Japan	28 / Female	Lipstick	Propylene glycol ricinoleate	Own lipstick ++, Propylene glycol ricinoleate (10% pet.) ++	Resolution of lesions
Denis Sasseville et al. 2011 (94)	Canada	19 / Female	Lip balm	Castor oil, Glycyrrhetinic acid	Own lip balm ++, Castor oil (5% pet.) ++, Glycyrrhetinic acid (0.02% aq./alc.) ++	NM
Inoue et al. 1998 (95)	Japan	24 / Female	Lipstick	Ricinoleic acid, Ester gum (Rosin)	Own lipsticks +, Ester gum (30% pet.) +, Gum rosin (20% pet.) +, Ricinoleic acid (10% pet.) ++	NM
Batta et al. 1997 (96)	UK	58 / Female	Lipstick	Colophony (Rosin)	Positive to colophony and lipstick	Resolution of lesions
Ichihashi et al. 2003 (97)	Japan	27 / Female	Lipstick	Pentaerythritol rosinate (Rosin)	Own lipstick ++, Pentaeryth	Resolution of lesions

					ritol rosinate ++	
Fraser et al. 2014 (98)	Canada	27/ Female	Lip balm	Rosin, lanolin	Lanolin +++, rosin+++	NM
Rademaker et al. 1986 (99)	UK	20/ Female	Lipstick	Colophony, shellac, Lanpol 5,	Own lipstick ++, Colophony ++, Shellac (100%) ++, Lanpol 5 (5% pet.) ++	NM
Linghong et al. 2018 (100)	Canada	18 / Male	Lip balm	Rosin, propolis, peppermint oil, limonene hyperoxide, linalool hyperoxide, eugenol, ylang ylang oil	Own lip balm +++, Rosin +++, Propolis ++, Limonene hyperoxide ++, Linalool hyperoxide ++, Ylang-ylang oil ++, Peppermint oil +, Eugenol +	NM
Powell et al. 2012 (101)	Canada	37 / Female	Lipstick	Ceresin wax	Own lipstick +, Ceresin (30% pet.) +	NM
Nuria Barrientos 2013 (102)	Spain	25/ Female	Lipstick	Candelilla wax	Own lip balm +++, Candelilla	Resolution of lesions

					wax (10% pet.) +++, Octyldodecanol +	
Jensen et al. 2006 (103)	Denmark	44/ Female	Lip balm	Propolis	Propolis (10% pet.) ++, Cera alba (20% pet.) +, Cera flava (30% pet.) +	Lesions improved after discontinuing the use of lip balm; nevertheless, the patient continued to experience dry and chapped lips
Jacob et al. 2008 (104)	USA	6 / Female	Lip balm	Carnauba wax and propolis	Positive to own lip balm, Propolis, and Cinnamaldehyde	Resolution of lesions
Alrowaishdi et al. 2013 (105)	Saudi Arabia	33 / Female	Lip balm	Carnauba wax	Own lip balm +, Positive to carnauba wax	Resolution of lesions
Molly et al. 2017 (106)	USA	17/ Female 65/ Female 42/ Female 62/ Female	Lip balm Lip balm Lip balm Lip moisturizer	Benzophenone-3 Menthol, propolis Propolis Carmine Benzophenone-3	Benzophenone-3 ++, Own lip balm ++ Menthol ++, Propolis +, Own lip balm ++ Propolis +, Carmine +, Own lip balm ++	NM

					Benzophenone-3 ++, Own lip moisturizer +	
Aguirre et al. 1992 (107)	Spain	20 / Female	Lipstick	Benzophenone-3	Benzophenone-3 (1% pet.) ++, Positive to lipstick	Resolution of lesions
Schram et al. 2007 (108)	Hennepin	45 / Male	Lip balm	Benzophenone-3	Benzophenone-3 (3% pet.) +++, Lip balm +++	Resolution of lesions
Veysey et al. 2006 (109)	UK	79 / Female	Lip salve	Benzophenone-3	Patch test negative, photo patch test was positive to benzophenone-3	Resolution of lesions
Hayakawa et al. 1987 (110)	Japan	18 / Female	Lipstick	Glyceryl monoisostearate and isostearyl alcohol	Own lipsticks ++, Glyceryl monoisostearate (0.01% pet.) ++, Isostearyl alcohol (0.25% pet.) ++	NM
Hemmer et al. 1997	Austria	29 / Female	Lipstick	NM	Negative patch test	Moderate brightening of

(111)						pigmentation started 6 months later
Mutsuyo et al. 2001 (112)	Japan	23 / Female	Lipstick	Glyceryl monoisostearate monomyristate	Own lipstick +, Glyceryl monoisostearate monomyristate (7% pet.) +	NM
Hyun et al. 2003 (113)	Korea	26 / Female	Lipstick	D & C Red no. 7	Positive to own lipstick, D&C Red no. 7 ++	Resolution of lesions
Calnan et al. 1981 (114)	England	71 / Female	Lipstick	Monotertiary butyl hydroquinone	Own lipstick +, Monotertiary butyl hydroquinone (1% pet.) ++	NM
Pastor et al. 2008 (115)	Spain	20 / Female	Lipstick	PVP/hexadecane copolymer and bisabolol	Own lipstick ++, PVP/hexadecene copolymer (5% pet.) ++, Bisabolol (5% pet.) ++	Resolution of lesions
Toshiko et al. 2008 (116)	Japan	38/ Female	Lipstick	Dipentaerythritol fatty acid ester (dipentaerythri	Positive to own lipstick and	Resolution of lesions

				tol, esters with hexahydroxystearate, stearate, and rosinate)	dipentaerythritol fatty acid ester (dipentaerythritol, esters with hexahydroxystearate, stearate, and rosinate) (1% pet.)	
Inui et al. 2009 (117)	Japan	28/ Female	Lipstick	Oleyl alcohol, diisostearyl maleate, glyceryl isostearate, lithol Rubine BCA	Own lipsticks ++, Oleyl alcohol (10% pet.) +, Glyceryl isostearate (1% pet.) +, Diisostearyl maleate (40% pet.) +, Lithol Rubine BCA (1% pet.) +	Resolution of lesions
Miura et al. 2011 (118)	Japan	38/ Female	Lipstick	Ditrimethylolpropane triethylhexanoate	Own lipstick +, Ditrimethylolpropane triethylhexanoate +	NM
Ravitasari et al. 2015 (119)	Indonesia	21/ Female	Lipstick	NM	Positive to own lipstick	NM

Quartier et al. 2006 (120)	Belgium	28/Female	Lipstick and Lip balm	PVP/hexadecene copolymer	Own lipstick and lip balm ++, PVP/hexadecene copolymer (10% pet.) ++	NM
Sasseville et al. 2009 (121)	Canada	38 / Female	Lip balm	D & C yellow 11	Own lip balms + and D&C Yellow 11 (0.0016% pet.) positive	NM
Franken et al. 2013 (122)	Netherland	46 / Female	Lip balm	Menthoxypropanediol	Menthoxypropanediol 5% ++, Menthoxypropanediol 2% +, Menthoxypropanediol 0.5% +, Lip balm ++	NM
Sarre et al. 2014 (123)	France	14/ Female 83 / Male	Lip stick Lip stick	Polysilicone-15 and bisabolol Polysilicone-15	Own lipstick ++, Polysilicone-15 10% pet. +++, Bisabolol 5% pet. + Own	NM

					lipstick +++, Polysilicone-15 10% pet. +++	
Prakash et al. 2020 (83)	India	17 / Female	Lip balm	NM	Patch test was not done	Resolution of lesions
Kerre et al. 2018 (124)	Belgium	20 / Female 55 / Male 51 / Female	Lip balm Lip balm Lip balm	Lauryl PCA	Lauryl PCA 20% pet. ++, Lauryl PCA 10% pet. ++, Lauryl PCA 5% pet. +, Lip balm ++ Lauryl PCA 20% pet. ++, Lip balm ++ Lauryl PCA 20% pet. ++, Lip balm ++	NM
Angelini et al. 1993 (125)	Italy	21 / Female	Lip liner	Para-tertiary-butyl phenol	Para-tertiary-butyl phenol 2% ++	NM
Mizuho Kimura et al. 2002 (126)	Japan	24 / Female	Lip gloss	Hydroxystearic acid and C18-36 acid triglyceride	Hydroxystearic acid 10% pet. +, C18-36 acid triglyceride 10% pet. +, Lip glosses +	NM

Ferguson et al. 1995 (127)	UK	13 / Female	Lip salve	Vanilla	Vanilla 10% pet. ++, Lip salve ++	Partially resolved
Hindle et al. 2007 (128)	UK	30 / Female	Lip salve	Citral	Citral 2% pet. ++	Resolution of lesions
Firoz et al. 2008 (82)	US	3 / Male	Lip plumper	Benzyl nicotinate and capsicum frutescence resin	Patch test was not done	NM

NM: not mentioned

2.2 Key Ingredients in Lip Cosmetics Triggering Allergic Contact Dermatitis

2.2.1 Gallate

Gallate is an ester of gallic acid and most commonly refers to propyl gallate, octyl gallate, and dodecyl gallate. These ingredients are used in cosmetics and emulsions to stabilize the products and prevent free radical-mediated oxidation (129). Oxidation in a cosmetic product is undesirable because it may lead to a change in color, odor, and deterioration of active constituents. Despite its usefulness in cosmetic formulation, it's not free from adverse effects. Apart from its application in cosmetics, gallate is also used as a preservative in processed food. However, allergic reaction to food, containing gallate was not reported. This may be due to immunological tolerance to orally administered gallate. An animal study reported moderate to strong contact sensitivity with all three gallates (130). The intensity of sensitivity is closely related to the length of the side chain present in the structure of gallates. As per US Food and Drug Administration, the permissible limit of gallate is 0.001% to 0.01% in cosmetic and topical medicines (131).

Gallate is widely used in lip care cosmetic products. A total of five cases were reported as dermatitis to gallates (84-88). Apart from one case of dermatitis related to both propyl and octyl gallate, all other four cases have been reported to develop the reaction due to propyl gallate. Propyl gallate is the most commonly used gallate in cosmetics. Thus, it is reported as the most commonly reported allergen in cosmetics.

A previous retrospective analysis of patch test results revealed that 0.6% of patients had positive reactions to propyl gallate (132). Another large hospital-based retrospective study reported that 2.5% (30/1173) of patients had positive patch test results for propyl gallate, 2.3% (27/1173) for octyl gallate, and 0.5% (6/1173) for dodecyl gallate (133).

2.2.2 Castor oil

Castor oil is a vegetable oil made from the seed of *Ricinus communis*. It is known that up to 90% of the fatty acids in castor oil are containing ricinoleic acid. Castor oil is the most frequently used ingredient in cosmetics. Ricinoleic acid has been depicted to be beneficial in preventing the growth of viruses, bacteria, yeasts, and molds. This would account for the oil's high rate of effectiveness when applied topically for curing conditions like ringworm, keratoses, fungal infections of the finger and toenails, acne, and pruritus (134). Hydrogenated castor oil is utilized as an emulsifier in skin creams since it is solid and doesn't hurt the skin (135). Among lip cosmetics, castor oil is used as an emollient, humectant, and pigment stabilizer (89, 93). Despite its several applications in cosmeceuticals, it’s not completely free from side effects.

Ricinoleic acid is the primary allergen of castor oil. There are a total of seven studies that have reported contact allergic reactions to castor oil or its components (89-95) . Five studies reported allergic reactions to lipsticks and the other two studies reported due to lip balm. Junoko et al. reported allergic contact dermatitis due to synthetic ricinoleate which is propylene glycol ricinoleate (93). It is a monoricinoleate of propylene glycol used as a humectant. Cross-reactions between ricinoleates may be the reason for the allergic reactions. Studies have also reported allergic reactions to synthetic ricinoleate present in deodorants (136, 137). Another study by Tan et al. reported a case of lipstick contact dermatitis due to the presence of oleyl alcohol, ricinoleic acid, and lanolin (92). The cross-reaction of oleyl alcohol with ricinoleic acid and lanolin could be the possible cause of the allergic reaction. A study by Danis et al. reported allergic reactions due to the castor oil and glycyrrhetinic acid present in lipstick (94). As both the components have entirely different chemical structures hence, the allergic reaction could be the result of a concomitant reaction. Another study by Sánchez-Herrero et al. presented a case of contact dermatitis in a pediatric

patient caused by castor oil in his lip balm (90). A hospital-based study from Singapore reported that out of 202 patients with contact cheilitis, 72 had allergic contact cheilitis, and lip cosmetic products were the most common cosmetics that showed contact cheilitis (138). Animal studies have also reported that undiluted castor oil has shown severe irritation to rabbit skin and mildly irritating to the guinea pig and rats' skin (139, 140).

2.2.3 Benzophenone-3

Benzophenone-3, also known as oxybenzone is a UV-absorbing agent, widely used in sunscreen. It is also used as a photostabilizer in mascara, lip balm, lipstick, lip salve, antiaging cream, and powder (141, 142). Benzophenone 3 is a very small molecule, which upon application on the skin passes through the stratum corneum by passive diffusion and reaches into the blood circulation (143). Animal studies reported that benzophenone-3, after topical application, can pass into the blood circulation and cross the blood-brain barrier, and the placenta (144). Thus, it can produce toxicities in the foetus. It can also produce toxicity to the endocrine system, reproductive system, and neurons (144).

However, apart from case reports, case series and few retrospective studies, the efficacy and safety data on humans from randomized controlled trials are lacking. A study has reported that it is the most common cause of allergic contact dermatitis in sunscreen products (145). We found a total of 5 cases of allergic reactions to benzophenone-3, of which 3 cases developed allergic reactions due to lip balm and 2 cases each with lipstick and lip salve (106-109). A retrospective study by Cook et al. reported a total of 19 cases of photoallergic reactions to sunscreen of whom nine were having positive photo patch reactions to oxybenzone and one to benzophenone (146). In another study on 219 patients with contact allergy to sunscreen agents, benzophenone 3 was the main allergen for the majority of patients (147). Therefore, lip cosmetics containing benzophenone 3 should be used cautiously.

2.2.4 Wax

Wax is a dull yellow solid plastic secreted by bees, primarily composed of a mixture of esters, hydrocarbons, and fatty acids. It is used by bees for constructing the

honeycomb. There are two types of waxes: natural and synthetic wax. Natural wax made from leaves and leaf buds of the *Copernicia prunifera*, a Brazilian carnauba palm, is known as carnauba wax. Carnauba was mostly consisting of fatty acid esters, fatty alcohols, and acids. There exist 2 cases of allergic reactions due to carnauba wax. In the first case, a 33-year-old woman developed allergic contact cheilitis due to carnauba wax present in her lip balm (105). In the second case, a 6-year-old girl experienced dermatitis in the upper extremity and showed positive results to patch test with carnauba wax and propolis (104). Apart from lip cosmetics, eyelid contact dermatitis after using mascara was also reported in which carnauba wax was the ingredient (148).

Another naturally occurring wax is candelilla wax that is used in lip care products. It contains a higher proportion of hydrocarbon compared to carnauba wax. It is commonly used in lip balm by mixing it with other waxes. There is only one case of candelilla wax in which a woman appeared at the hospital with an unusual flare-up of cheilitis which she was suffering since childhood (102). Due to their emollient qualities and highly glossy finish, both candelilla and carnauba waxes are widely used in a variety of cosmetic items, including mascara, lipstick, eye shadow, and eyeliner (16). Other wax is ceresin, obtained from naturally occurring mineral wax known as ozokerite. Due to its paraffin-like composition, it offers an excellent level of flexibility, adhesiveness, and water resistance. In its original state, ceresin is acceptable for use in cosmetics including lotions, mascara, and lipsticks. One case of allergic contact dermatitis has been reported after using lipstick (101). The patient showed positive patch test results with ceresin which was a component of the patient's lipsticks. Propolis is another wax, used in lip care products found to have allergic reactions. It is resinous products that is produced by bees. It contains a mixture of resin, pollen, essential oil, wax, and other organic substances. It is extensively used in the cosmetics, medicine, and food industries. It is one of the most frequent contact sensitizers reported in children and adolescents. Even acute renal failure was reported after the consumption of propolis, which was improved after stopping propolis (149). A total of 5 cases of allergic contact dermatitis to propolis have been reported (100, 103, 104, 106). In all cases, propolis was used as an ingredient in the lip balm. Patch test results of all 5 cases were found positive.

Overall, a total of 8 cases of wax induced allergic contact dermatitis were found in the present study, of whom one patient developed the reaction due to carnauba wax, four patients due to propolis, one patient due to both carnauba wax and propolis, and the remaining 2 patients each with ceresin wax and candelilla wax (100-106). All the cases showed positive patch test results with these waxes. The presented reports highlight the importance of testing patients' own lip care products if wax remains as an ingredient in their lip care cosmetics.

2.2.5 Colophony

Colophony also known as rosin. It is a substance obtained from coniferous trees. Owing to its easy availability, low cost, and excellent tackifying qualities, its popularity is increasing in the last decade. Rosin is used for preparing the film, paint, coating, adhesive, metallurgy, and construction. Apart from this, it also has a wide range of applications in the biomedical and cosmeceutical industries. In cosmetics, the modified form of rosin is used as an emulsifying agent in the formulation of lipstick, mascara, eyeliners, hair care products, foundation, and lip care products (150). Allergic contact dermatitis to rosin have been reported in many different cosmetics. A study from India reported contact dermatitis due to rosin derivative uses as an adhesive in Indian bindi (151). We found a total of 6 case reports of allergic contact dermatitis to rosin or its derivatives (96-100). Four patients developed the reaction due to rosin and two cases were due to its derivatives; ester gum and pentaerythritol rosinate. The patch test results showed a positive reaction exclusively to the rosin in two patients (96, 98). Among the remaining 4 cases, in addition to rosin, positive patch test results were obtained with lanolin, ricinolic acid, shellac, lanpol 5, propolis, and many other components of lip care products (97-100).

2.2.6 Lauryl PCA and other ingredients

Lauryl PCA is another ingredient that is used as a humectant in lip balm. A case series study from Belgium reported cheilitis with Lauryl PCA in 3 patients (124). Lauryl PCA is an ester formed from L-pyrrolidone carboxylic acid and lauric alcohol (124).

Lip salve is a less commonly used lip care product that reported allergic reactions to flavouring agents. Two different case studies have reported allergic reactions to citral

and vanillia (127, 128). Citral is a naturally occurring product with a strong lemon odour. It showed positive patch test reactions in 4.3% of patients with hand eczema in the previous study (152). Another study from Europe reported that 1.1% of consecutive patients had positive patch test reactions with citral (153). Vanilla is a naturally occurring product obtained from *Vanilla Planifolia*. Apart from cosmetics, it is also added to sweets and cakes. Allergic reaction to vanilla was also reported among bakers and beverage makers and those growing and processing it (154).

2.3 Eye cosmetics and adverse effects

Eye cosmetics now have become a part of our daily life across several parts of the world (155). Eye cosmetics like eyeliner, mascara, eyelash extension, Surma, and eye shadow are broadly used to beautify the eyes and preservatives present in the eye cosmetics inhibit the microbes (156). There are several adverse effects of eye cosmetics which includes Allergic contact dermatitis, conjunctival melanoma, Dry eye syndrome, Lacrimal obstruction, Occupational asthma, Occupational rhinitis, Ocular disorders, such as keratoconjunctivitis and allergic blepharitis. Several cases were reported where the utilization of products such as mascara and eyeliner cause conjunctival pigmentation, which ranges from diffuse pigmentation of tarsal conjunctiva to discrete, punctate deposits. Composition of eye cosmetics is given in Table 2. Eye cosmetics products and their adverse effects summarized in Table 3.

Table 2. Formulation of eye cosmetics

Formulations	**Composition**
Base	Water and Oil
Thickeners	Waxes, polymers, and gels
Pigments	Iron oxide, Chromium, ultramarines, Manganese Violet, Titanium dioxide, Zinc oxide etc.
Preservatives	Parabens, phenoxyethanol, and benzyl alcohol
Emulsifiers	Glyceryl stearate, Steareth-2 andisoceteth
Film formers	Silicone and acrylate polymers
Antioxidants	Vitamin E and rosemary extract
Active ingredients	Panthenol

Table 3. Eye Cosmetics Products and their Adverse Effects

S. No.	Eye cosmetics products	Adverse effects
1.	Mascara	Eyelid dermatitis(155-157) Conjunctival melanoma(158), Conjunctival lesions, Dry eye syndrome, Lacrimal obstruction(159), Palpebral conjunctival lesions(160)
2.	Eyelash extension	Kerato - conjunctivitis and allergic blepharitis(161)
3.	Eye makeup removers	(Facial eczema) Goones(162)
4.	Eye cream	Contact dermatitis(160), Posterior corneal folds, (epithelial pigmentation. Pigmentation of scleral and corneal folds) (163), Bilateral keratitis, blepharo-conjunctivitis(164)
5.	Coloured contact lenses	Keratitis (165)
6.	Kajal	Lead poisoning(166)

2.3.1 Mascara

Mascara is a cosmetic product that is primarily used to enhance and define eyelashes. The ingredients of mascara consist of solvents, waxes that are obtained from animals or plants. Prolonged use of mascara may cause several ocular complications (160). Cosmetic and mascara use has been linked to various eye-related issues, such as allergic contact dermatitis and corneal ulcers caused by the bacteria Pseudomonas. These findings have been reported in studies and research on the subject (160). These all are the adverse effects occurred by the shellac which is we have already discussed above. Shellac is a resinous product secreted by the fly Laccifer (Tachardia) lacca. Widely used by pharmaceutical and cosmetic industries. Which is present in mascara, causes eyelid dermatitis allergic contact dermatitis of the eyelids has been linked to mascara use. Several cosmetic products, including mascara, contain iron oxides as pigments. Allergic contact dermatitis of the eyelids has been linked to mascara use. According to the manufacturer, only 5% of the black iron oxide used in mascara formulation may cause allergic reactions (155, 156).

2.3.2 Eyelash Extension

Eyelash extensions are a cosmetic enhancement procedure in which individual artificial lashes are applied to a person's natural lashes, giving the appearance of longer, fuller, and thicker lashes. In recent years, there has been a significant increase in the global popularity of cosmetic enhancements, with procedures such as eyelash extensions becoming increasingly popular among individuals seeking to enhance their appearance (167). Despite the rising popularity of cosmetic procedures, there are numerous negative effects associated with them that are often unknown to both users and medical professionals. These effects can range from mild discomfort to serious allergic and chemical reactions caused by the products and techniques used during the procedures. The usage of eyelash extensions has been linked to eye problems like allergic blepharitis and keratoconjunctivitis (161, 167). The adhesive products commonly used for attaching eyelash extensions are typically based on cyanoacrylate, which have a high formaldehyde emission and may contain latex and ammonia. These ingredients have been known to cause several adverse reactions, including contact dermatitis, toxic conjunctivitis, allergic blepharitis, conjunctival erosion, and bacterial keratitis (167). A study showed that the adverse effects of cyanoacrylate are Contact dermatitis, toxic conjunctivitis, allergic blepharitis, conjunctival erosion, and bacterial keratitis. Ethyl cyanoacrylate, which is one of the cyanoacrylate glues used at a concentration of 10% causes eyelid and facial dermatitis (161, 167).

2.3.3 Eye-Makeup Remover

Eye makeup removers are products specifically designed to remove makeup from the delicate skin around the eyes. The skin in this area is thinner and more sensitive than other areas of the face, which makes it important to use gentle and effective products for makeup removal. There are several types of eye makeup removers available, including oil-based, water-based, and bi-phase removers. When using an eye makeup remover, avoid rubbing or pulling at the eye area, as this can cause irritation or damage to the delicate skin. Eye makeup remover causes the several adverse effects like, (Facial eczema) Goons (162). A member of the class of alkylamido alkylamides, sodium cocoamphoacetate is an amphoteric surfactant. These substances are all produced by the condensation of fatty acids and aminoethyl ethanolamine and are

frequently used in hair and skin cleansing products, hair conditioning products, and hair dyes in concentrations ranging from 0.1% to 50%. In addition to cosmetics, they are used in pharmaceuticals for the treatment of glaucoma and haemorrhoids, contact lens cleaners, bandage materials, and home and industrial items including paints and dishwashing and laundry detergents. Amphoacetates are typically combined with other surfactants and are regarded as moderate irritants (162).

2.3.4 Eye creams

Eye cream is a type of skincare product that is formulated specifically for the delicate skin around the eyes. It is designed to address common issues such as fine lines, wrinkles, dark circles, and puffiness that can occur in this area. Eye creams typically contain ingredients such as retinol, peptides, antioxidants, and hyaluronic acid, which work together to moisturize, brighten, and firm the skin. The adverse effects associated with Eye creams include conjunctival and scleral pigmentation, Bilateral keratitis, acute right eye pain, photophobia, and lacrimation. Bilateral infectious keratitis typically occurs in individuals with identifiable risk factors such as trauma, surgery, contact lens use, or malnutrition. There has been only one study of bilateral keratitis caused by Pseudomonas aeruginosa occurring without any apparent predisposing factors (168). According to the only published article in the field of ophthalmology that addresses the topic of eye changes in individuals who use skin-lightening creams, a study of 72 cream users showed that 26% of them had developed pigmentation in the conjunctiva. The primary active ingredient in skin-lightening creams is hydroquinone. This compound works by disrupting the production of melanin in specialized skin cells called melanocytes. It does so by inhibiting the enzymatic process that converts tyrosine into 3,4-dihydroxyphenylalanine, a necessary step in melanin synthesis. As a result, the skin becomes lighter in color as melanin production is reduced (163).

2.3.5 Colored contact lenses

Colored contact lenses are a type of corrective lens that are designed to enhance or change the color of a person's eyes. They are made of the same materials as regular

contact lenses, but they have an added layer of color that can alter the appearance of the iris.

Soft hydrogel non-corrective contact lenses, also known as plano or zero power lenses, are primarily prescribed and used for cosmetic purposes to modify the appearance of the eye. These decorative contact lenses are designed to change or enhance the natural color of the eyes, and they come in various colors and designs to achieve different aesthetic effects (169). Similar corrective contact lenses, decorative or ornamental lenses can pose a risk to eye health if they are not worn properly. Wearing these lenses without proper fitting or care can lead to eye irritation, infection, or other complications that can potentially harm the eyes. The study highlights a concerning trend happening in the United States, which involves the unauthorized sale of decorative hydrogel contact lenses with zero power (plano) by non-eye care professionals. This unlicensed distribution of contact lenses poses a significant risk to public health, as consumers may purchase and wear these lenses without proper fitting or care instructions, leading to severe eye problems or vision damage. In June 2002, the American Academy of Ophthalmology initially received reports regarding the illicit sale of plano decorative contact lenses that were available over the counter, without a prescription (165, 169). The adverse effects associated with coloured contact lenses are ring keratitis^{2} (Atypical, Pseudomonal), pain and epiphora, stromal ring infiltrate, tear film debris, large central infiltrate and hypopyon, mild punctate keratopathy, herpes simplex keratitis, subconjunctival haemorrhage, microcystic and stromal edema, giant papillary conjunctivitis, acute iridocyclitis (165, 170).

2.4 Hair dye and adverse effects

The adverse effects of hair dyes have been a topic of concern for many years. This review paper aims to provide an overview of the various adverse effects associated with the use of hair dyes and the current state of research in this area. Studies reporting adverse effects of hair dyes along with their chemical constituents are summarized in **Table 4**

Table 4. Adverse events associated with hair dyes

Author (Year); Country (Ref)	Study Design	Patient(s) Description	Suspected Constituent(s) of Hair Dye	Adverse Event(s)
Patra et al. (2015); India (171)	CR	24-year-old female	PPD	Hair dye poisoning (acute PPD poisoning with angioedema, rhabdomyolysis, metabolic acidosis, and acute renal failure)
Senthilkumaran et al. (2011); India (172)	CS	20-year-old female 18-year-old female	PPD	Hair dye poisoning (alert and acyanotic status with tachypnoea, tachycardia, and hypotension)
Chaudhary et al. (2013); India (173)	CR	15-year-old female	PPD	Hair dye poisoning
Ryoo et al. (2014); Korea (174)	CR	30-year-old male	PPD	Hair dye poisoning
Midha et al. (2009); India (175)	CR	14-year-old boy	PPD	Hair dye poisoning
Beshir et al. (2017); Sudan (176)	CR	14-year-old female	PPD	Hair dye poisoning
Waka et al. (2011); Japan (177)	CR	41-year-old female	PPD	Contact dermatitis

Işik S et al. (2017); Turkey (178)	CR	15-year-old female	PPD	Contact dermatitis
Wilkinson et al. (2019); UK (179)	CR	54-year-old male	PPD	Contact dermatitis
Lönngren et al. (2012); Sweden (180)	CR	58-year-old female	PPD	Contact dermatitis
Ngwanya et al. (2018); South Africa (181)	CR	29-year-old female	PPD	Contact dermatitis
Genderen et al. (2014); Netherlands (182)	CR	33-year-old female	PPD	Contact dermatitis, severe facial edema
Gatica-Ortega et al. (2022); Spain (183)	CR	24-year-old male	PPD	Contact dermatitis, alopecia
Dev et al. (2021); India (184)	CR	30-year-old female	PPD	Contact dermatitis, alopecia
Trattner et al. (2007); Israel (185)	CR	58-year-old male	PPD, p-aminophenol	Contact vitiligo
Søsted et al. (2005); Denmark (186)	CR	50-year-old female	3-Nitro-p-hydroxyethylaminophenol, 4-amino-3-nitrophenol	Contact dermatitis

Uehara et al. (2014); Japan (187)	CR	52-year-old female	p-aminophenol, Sodium-methyl-oleoyl-taurate	Contact urticaria
Oshima et al. (2001); Japan (188)	CR	61-year-old man	p-aminophenol, para-methylaminophenol	Contact dermatitis
Dandorf et al. (2016); USA (189)	CR	22-year-old female	PPD, Black henna	Contact dermatitis
Broides et al. (2011); Israel (190)	CR	15-year-old female	Black henna	Contact dermatitis
Wolf et al. (2006); Israel (191)	CR	44-year-old woman	Black henna	Contact dermatitis
Lee et al. (2016); Korea (192)	CR	64-year-old female	Natural henna	Contact dermatitis
Voller et al. (2020); USA, Canada (193)	CR	50-year-old female	Natural henna, PPD, toluene-2,5-diamine sulfate	Contact dermatitis
Ellis et al. (2009); UK (194)	CR	47-year-old female	PPD, 4-Amino-2-hydroxytoluene	Contact dermatitis
Sowa-Osako et al. (2021); Japan (195)	CR	29-year-old female	PPD, PTD	Contact dermatitis, anaphylactoid reaction

Montgomery et al. (2017); UK (196)	CR	64-year-old female	PPD, resorcinol, toluene-2,5-diamine, m-aminophenol, cetyl alcohol, benzoic acid, diethanolamine, sodium metabisulfite, propylene glycol	Contact urticaria
Field et al. (2007); Ireland (197)	CR	47-year-old female	TBHQ, Laureth 12, BHA	Contact dermatitis
Yawei et al. (2021); China (198)	CR	44-year-old woman	Mercury	Peripheral neuropathy and Guillain-Barre syndrome
Hougaard et al. (2012); Denmark (199)	CR	18-year-old female	Ammonium persulfate, Potassium persulfate	Allergic contact eczema and asthma
Maguina et al. (2007); USA (200)	CR	16-year-old female	Hydrogen peroxide, Ammonium persulfate, Potassium persulfate	Chemical burn
Deeb et al. (2014); USA (201)	CR	52-year-old man	Lead	Peripheral neuropathy

Jensen et al. (2006); Denmark (202)	CS	12-year-old female 26-year-old female	NM	Chemical burn Chemical burn

ME-PPD: 2-methoxymethyl-p-phenylenediamine; PTD: toluene-2,5-diamine; ACD: acute contact dermatitis; NA: not available; NM: not mentioned; CR: case report; CS: case series

2.4.1 Allergic contact dermatitis

One of the most significant adverse effects of hair dyes is allergic contact dermatitis (ACD) (178-184, 188-195, 197, 203-206). ACD is an immune-mediated reaction that occurs when an individual's immune system reacts to a specific allergen. The allergen is usually one of the components of the dye, such as p-phenylenediamine (PPD). Hair dyes contain various components that can cause a range of adverse reactions. Paraphenylenediamine (PPD) is commonly used to retain color (207) but is highly sensitizing and can cause contact dermatitis and hypersensitivity reactions (176, 208). Occupational hazard is associated with its use, particularly for hairdressers who frequently come in contact with the allergen (207). Ingestion of PPD can cause systemic toxicities such as methemoglobinemia, motor paralysis, angioedema, vomiting, renal failure, rhabdomyolysis, hepatic necrosis, pulmonary edema, laryngeal edema, and airway obstruction (172-176, 209). Contact with PPD can also lead to significant allergic reactions on skin and hair loss (177-180, 183, 184, 191, 210, 211). PPD is also believed to be a carcinogenic agent causing mutations in human genetic structure and leading to breast cancer (212, 213). Henna, commonly used as a hair dye and for body art, can cause contact dermatitis (190, 192, 193), particularly black henna which contains PPD. Cases of delayed-type hypersensitivity reaction, contact dermatitis, and swelling of soft tissues due to direct contact with PPD have been reported (189, 191). Traces of PPD as a contaminant in henna have also led to complications in some cases (193). In one case, facial hyperpigmented lesions remained even after the inflammation had resolved (192). Hair dyes may also contain toxic elements such as mercury and lead, which can cause peripheral neuropathy and Guillain-Barre syndrome as a result of high intoxication (198, 201).

Both these elements act as neurotoxicants because of their ability to cross the blood-brain barrier and damage the central nervous system (198, 201). Occupational hazards are associated with oxidizing agents in hair dye, such as hydrogen peroxide, ammonium persulfate, and potassium persulfate, leading to scalp burns, ulcers, necrotic eruptions, hair loss, asthma, and hand eczema in hairdressers (200). This is because they cause protein denaturation at the site of contact due to their oxidizing nature (200). Hair dyes can also contain p-toluenediamine (PTD), which can cause combined immediate and delayed hypersensitivity reactions leading to vomiting, nausea, shortness of breath, and scaly lesions on the scalp (195). Contact urticaria and contact dermatitis can also be caused by cross-reactions among the constituents present in it (196, 197). Sensitization to components such as 4-amino-2-hydroxytoluene, aminophenols, sodium-methyl-oleoyl-taurate, and para-methylaminophenol can induce immune responses (187, 188) and lead to complications such as pruritic scalp dermatitis, facial and thoracic edema (186), and even vitiligo (185).

2.4.2 Hair dye poisoning and suicides

Hair dye poisoning can have severe and potentially fatal outcomes, such as pneumothorax, rhabdomyolysis, and acute kidney injury (AKI) (172, 214, 215). Due to its easy availability and high toxicity, people in developing countries may attempt suicide by consuming PPD (216), a common ingredient in hair dyes. Ingesting PPD can cause trauma to the airway, leading to respiratory distress and chest pain. Those suffering from these symptoms should be cautious of the occurrence of pneumothorax, which can be diagnosed through sonography or bedside X-ray. Rhabdomyolysis is caused by calcium ions leaking from the smooth endoplasmic reticulum, resulting in irreversible muscle damage (217). AKI affects over 13 million people globally, with over 1 in 10 losing their lives from the disease (218). Hair dye-induced acute kidney injury (AKI) occurs in a dose-dependent manner, but the affected kidney may recover over time without any intervention (217).

2.5 Cosmetics usage pattern, knowledge, attitude and associated adverse reaction: Prevalence of cosmetic-induced adverse events both within India and globally, alongside the utilization patterns of various types of cosmetics, as well as the knowledge and attitudes of cosmetic usage and adverse events is discussed in (Table 5).

Table 5. Cosmetic utilization pattern, knowledge, attitude and adverse reactions associated with cosmetics

Year, country	Author	Study design	Sample size	Finding
2012, Iran	Hosseini et al.(219)	Cross-sectional study	540	The average age of the respondents was 21.3 years. The primary motivations for using cosmetic products were feeling beautiful (52.6%) and boosting self-confidence (20.9%). The most commonly used cosmetic products among students were lipstick (62.2%), mascara (50.9%), and eyeliner (43.3%).
2012, Iran	Jalilian et al. (220)	Cross-sectional study	540	Among students, lipstick (62.2%), mascara (50.9%), and eyeliner (43.3%) were the prevalent choices for cosmetic usage. The primary motivations behind the use of cosmetic products were feeling beautiful and enhancing self-confidence.
2013, Ethiopia	Dibaba et al.(221)	Cross-sectional study	726	The study revealed that 97.8% of respondents were regular cosmetic users, with body lotion being the most frequently used product. Adverse effects were reported by 18.4% of participants, mainly affecting the face, hair, and skin. Deodorants and lotions were identified as the main triggers of these reactions.

2013, Brazil	Huf et al. (222)	Cross-sectional study	200	Around 38% of participants experienced adverse reactions, primarily due to soap, shampoo, and deodorants. Reactions were mostly dermatological, with symptoms like skin redness. While most reactions were mild (56.6%), 9.2% were severe, requiring medical treatment.
2014. Ethiopia	Binega et al.(223)	Cross-sectional study	242	The study found that 30.16% of women and 69.83% of men experienced cosmetic-related adverse reactions. Among the 85% of respondents who used cosmetics, moisturizers and deodorants were the most common products. Skin rash, with a prevalence of 15.7%, was the most frequent reaction.
2014, Ethiopia	Meharie et al.(224)	Cross-sectional study	214	The study found that participants, with an average age of 22.5 years, used 3.34 cosmetic products daily. Lotions and hair cosmetics were most common cosmetics. Common practices included adding water/saliva (79.9%) and sharing products (77.1%). Only 33.2% read labels, and 31.8% reported adverse effects like itching, acne, and skin sores.
2016, Nepal	Shrestha et al.(225)	Cross-sectional study	70	Among 70 respondents, 30% were 17 years old, and 51.4% were in grade 12. Adverse effects from cosmetics were reported by 34.3%, with acne being the most common (50%). While all knew lipstick can cause lip cancer, knowledge levels varied: 72.9% had average knowledge, 17.1% had low, and 10.0% had high levels.
2016, Ethiopia	Bilal et al.(226)	Cross-sectional	601	The average age of respondents was 21.8 years, with 76% female and 78% single. Most used

		study		cosmetics for "cleansing," favoring body creams/lotions (68%), shampoos/conditioners (35%), and deodorants/perfumes (29%). Quality was prioritized by 70%, and 62% used cosmetics daily, with 74% using them more than once daily. Most purchased from supermarkets (68%), and 89% read labels, mainly for expiry dates (39%).
2016, Saudi arabia	Helali et al.(227)	Cross-sectional study	400	A significant proportion of girls aged 15-25, 64% preferred smoothness and moisturizing creams (58%), sun protection creams (17%), and some treated cosmetics as drugs (7%). Purchase habits revealed 11% didn't check ingredients, 50% avoided cheap lotions, and 13% didn't specify products. Education influenced their responses to ads and purchasing behavior, with most having satisfactory knowledge. Mild to moderate side effects were common, while severe effects from cortisone were rare.
2017, Ethiopia	Bilal et al.(54)	Cross-sectional study	600	The study found that 76% of participants were female, with 55.5% aged 18-20. Common products included shampoo (33%), deodorant (27%), and face powder (16%). About 44% used both traditional and modern cosmetics. Adverse reactions were reported by 61%, with allergies (36%) and acne (16%) being the most common. Some sought medical advice (35.4%) or temporarily stopped use (27%).
2018, Iran	Dehvari et al. (55)	Cross-sectional	200	The study included participants with a mean age of 29.22 ± 9.07 years. On average, they

		study		scored 5.95 ± 2.47 in knowledge about cosmetics. The mean score for participants' attitude and practice about using cosmetics was 31.80 ± 3.96, and 12.92 ± 2.83 respectively.
2018, Ethiopia	Getachew et al. (228)	Cross-sectional study	426	Participants had a median age of 28 years. Most commonly used cosmetics were lipstick, lotion, toothpaste, and eye makeup. Adverse events included hair breakage, body rash, itching, nasal congestion, scalp sores, eye redness, and lip cracks, with the face being the most affected area (36.8%). In response, 59.6% stopped using the suspected product, 14.0% sought medical consultation, and 17.5% permanently discontinued all cosmetic use..
2019, Lithuania	Šniepienė et al. (229)	Cross-sectional study	336	Commonly used products included soap, toothpaste, deodorants, and facial cream. Women aged 41 and above preferred eye oils and creams more than younger women. Side effects, primarily from mascara, eye shadows, and powders, included skin and eye irritation. About 80.4% of participants experienced adverse effects, with 67.1% reporting skin irritation and 57.1% experiencing eye irritation and eyelid swelling.
2020, Mysuru	Jyrwa et al. (230)	Cross-sectional study	87	The study reported an adverse event incidence of 0.38%. Most participants were aged between 21-30 years. Hair was the most common area of application for cosmetics resulting in adverse events (52.87%). Hair care products were the main suspects (51.72%), followed by soaps (14.94%) and skin creams (13.79%). Adverse

				events were predominantly associated with hair dye (17.24%) and shampoo (32.18%). Most participants (73.56%) discontinued the suspected cosmetics and received symptomatic treatment.
2020, Tanzania	Kureh et al. (231)	Cross-sectional study	112	Most of the participants (61.6%) was in the 20-24 age group. Over half (58.04%) reported adverse effects, with allergic reactions being the most common (30.8%). Perfumes were the leading cause of reactions (40%), followed by face products (21.5%), lotions (16.9%), and hair cosmetics (10.7%). Awareness of adverse effects mainly came from friends and family (29.5%), media (23.2%), and the internet (21.4%).
2020, Saudi Arabia	Shabaan et al.(232)	Cross-sectional study	709	The study found that 82.2% of participants were young females and 17.8% were senior females. Over 50% used 18 personal care products, with shampoo (100%) and conditioner (68%) being universally used. Hand lotion/cream (95%) and deodorant (91%) were popular. Young females favored nail polish/remover, while senior females preferred hair dye, anti-aging cream, and tanning products. Adverse events were reported by 16.1% of users, with common issues including redness, itching, skin soreness, hair breakage, eye inflammation, darkening of armpits, and face discoloration.

2020, Saudi Arabia	Lucca et al. (233)	Cross-sectional study	425	Around half of the participants (50.6%) experienced at least one adverse reaction in the past two years. Reactions were primarily caused by hair care (29%) and skincare products (25%). Most participants (84.2%) managed their reactions by stopping use. Factors such as medication allergies, family history of allergies, and mixing cosmetics were significantly associated with adverse reactions.
2021, Nepal	Laxmi et al.(234)	Cross-sectional study	80	The survey found that 47% of respondents were under 17 years old. Reasons for using cosmetics included attractiveness (50%), skincare concerns (17.5%), and boosting confidence (15%). Preferences of cosmetics was natural/herbal cosmetics (53.8%) and a mix of artificial and natural (13.8%). While 68.8% believed long-term use was beneficial, 31.2% experienced negative effects. About 28.7% reported substantial knowledge about cosmetics.
2022, India	Manjula et al.(235)	Cross-sectional study	300	Maximum participants (57%) were in the age group of 21-25 years. 40% of the customers prefer cosmetics for skin protection in humid and winter seasons. Majority (81.7%) users face no issues with branded cosmetics, while 7.7% experience facial cosmetic problems. 4.7% encounter skin issues due to chemical ingredients. In total 48.7% had a positive knowledge, attitude and practice. There was significant relationship between knowledge, attitude and practice.

2022, Saudi Arabia	Alsharif et al.(236)	Cross-sectional study	710	The study revealed that a significant portion of respondents (54.8%) were aged 18 to 30. Skincare product usage was prevalent. Physicians were the primary source of skincare information (64.1%), and the study emphasized the need for a comprehensive awareness campaign, considering the influence of gender and skin type on skincare behavior. Overall, the study found positive skincare knowledge and practices among participants.
2022, Egypt	El emam et al.(57)	Cross-sectional study	790	Reported prevalence of the study was 84.7%. Approximately 87.5% of students reported using cosmetic products. Factors such as age, residence, family size, and income were identified as significant predictors of cosmetic use. Only 21.9% checked if their cosmetics were tested on animals, and 46.7% tested for allergic reactions. cosmetics induced adverse effects was acne, redness, darkening of the armpits, itching, eye inflammation, hair breakage, soreness, facial discoloration, skin burns.
2022, Ethiopia	Addis et al.(53)	Cross-sectional study	338	Prevalence of cosmetic induced adverse effects was found to be 65.1%. The mean age of the female students was 20.43 years. Cosmetic use was diverse: beautification (55.33%), protection (20.42%), cleaning (18.93%), coloration (4.14%), and medications (1.18%). Only 35.21% conducted allergy tests before using cosmetics. Total 220 adverse effects were linked to lotions, hair cosmetics, deodorants,

				and body cream. Hair breakage (45.9%), skin allergy, and soreness (45.5%) were common issues. 50.89% consulted medical personnel.
2023, Lebanese	Chahine et al. (237)	Cross-sectional study	1,051	The majority of participants (70.8%) were aged between 18 and 20. A significant proportion (62.6%) were classified as knowledgeable based on their mean knowledge score of 7.54 ± SD 2.70.

CHAPTER - 3

3. Aim & objectives

3.1 Aim: Cosmetic utilization and associated adverse events: prevalence and risk factors analysis.

3.2 Objectives:

1. To evaluate the cosmetic utilization pattern and adverse events associated with it.

2. To assess the causality and the outcome of adverse events to cosmetics.

3. To determine the prevalence and risk factors of cosmetic-induced adverse events by conducting a systematic review and meta-analysis.

4. To assess the knowledge and attitude regarding cosmetic utilization and associated adverse events.

CHAPTER - 4

4. Methodology

4.1 Study design and setting

A cross-sectional study was conducted among the general population in Jalandhar, Amritsar and Ludhiana region of Punjab, India. The province of Punjab divides into the three geographical regions Doaba, Majha, and Malwa. From each region, one major city such as Jalandhar, Amritsar, and Ludhiana were selected. This study was conducted from May 2021–September 2022.

4.2 Study population

Participants' selection was done on the basis of pre-defined inclusion and exclusion criteria.

4.2.1 Inclusion criteria

a) Residents of Jalandhar, Amritsar and Ludhiana were included in the study irrespective of their nationality and gender.

b) Person who has a habit of using any categories of cosmetic products and who can read/ write either English, Punjabi or Hindi.

c) Age ranging from 15 to 50 years were invited to participate in this study.

d) Willingness to participate in the study by providing signed informed consent form.

4.2.2 Exclusion criteria

a) Persons with hearing and sight problems.

b) Persons with tattoos, plastic surgery, filler and botox usage.

4.3 Sample size

The number of participants included in this study was decided by analyzing the percentage of population experienced adverse events in previously related study. A formula $n = Z^2 * P(1-P)/d^2$ was used for calculating the sample size, where n = sample size, Z = 1.96, for 95% confidence interval, d = 5%, degree of precision and P = 50%,

taken from previous study(233). The sample size was coming out to be 384. Considering 4% non-response rate, final sample size was found to be 400.

4.4 Data collection

A structured self-administered questionnaire was designed by referring the previously published articles and modified as per the study requirements(54, 233). Designed questionnaire consisted of both open ended and close ended questions. Initially the questionnaire was developed in English and was translated into Hindi and Punjabi. Hindi is the national language of India and Punjabi is the local language of Punjab. The twenty-five-items questionnaire was broadly categorized into three sections; Section A consisted of sociodemographic details of participants such as age, gender, marital status, residence, income, occupation, education, and personal and family history of allergy (Q1-Q8), section B consisted of questions related to utilization pattern of cosmetics such as type of cosmetic use, number and frequency of use, reason for use, read the instruction before application etc. (Q9-Q20) and section C consisted of questions related to adverse events of cosmetics such nature and type of event, cosmetics used, location and management of reactions (Q21-Q25).

4.5 Validation

The content validity of the questionnaire was done by five experts from diverse background comprising of clinician, biostatistician, doctorate academic pharmacists. All the experts had prior experienced in questionnaire-based study. The content validity of the questionnaire was assessed as per the Lawshee method(238). The content validity index (CVI) of the questionnaire (S-CVI/Ave) was determined by averaging the I-CVIs for each item on the questionnaire. S-CVI/Ave was found to be 0.98. Face validation was done by distributing questionnaire to 20 participants in community. These 20 questionnaires were not included in the final results. Reliability assessment of the scale was done by test-retest method by distributing questionnaires to the same sample of respondents at different times. Pearson's correlation coefficient was used to compute and compare the score. The calculated value of correlation coefficient was found to be 0.71, indicating high test-retest reliability.

4.6 Administration of questionnaire

The questionnaire was distributed to the public in the different places like schools, colleges, shopping malls, medical stores, general stores, market, hospitals, and park. Convenient sampling method was chosen to select the study participants. Participants were explained about the purpose of the study and they were also asked to read the questionnaire and informed consent before filling the questionnaire. A face-to-face interview was conducted by investigator in case of illiterate participants. The questionnaires were evaluated for their completeness and only the completed questionnaires were taken for the final analysis.

4.7 Ethical consideration

The study protocol was approved by the Institutional Ethics Committee of Lovely Professional University (Ref. no.: LPU/IEC/2021/01/33). Written informed consent was taken from the all the participants.

4.8 Data analysis

The collected data was analyzed using SPSS (Statistical Packages for Social Sciences) software version 16. Descriptive statistics (number and percentage) were used to summarize demographic characteristics, the pattern of cosmetic use, and adverse event. The factors associated with the occurrence of adverse events were evaluated using a logistic regression model. The multivariable logistic regression model was used to those variables that were found to be associated with outcome variable in bivariate analysis with $P < 0.20$. To demonstrate the degree of relationship and the statistical significance of the predictors, the adjusted odds ratio (AOR) and its 95% confidence interval (CI) were utilized.

4.9 Causality assessment

Causality assessment was done by using Colipa scale (239). A team of experts has developed a systematic approach for assessing adverse effects potentially linked to cosmetic products. It relies on six criteria, categorized into two groups, to compute both a chronological score and a semiological score. The determination of causality level is based on a decision table where the scores are combined. The method

categorizes causality into five levels: “very likely,” “likely,” “not clearly attributable,” “unlikely,” and “excluded.”

4.10 Assessment of prevalence and risk factors of cosmetic-induced adverse events by conducting a systematic review and meta-analysis

4.10.1 Study design

We performed a meta-analysis of primary studies that reported the prevalence of adverse events caused by the application of various cosmetics, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (240).

4.10.2 Literature search

A computerized search of the literatures published until August 2023 was conducted using different databases such as PubMed, Embase, Scopus, and Google Scholar. The following keywords were used: “adverse reactions,” “adverse events,” “adverse effects,” “side effects,” “suspected adverse reactions,” “undesirable effects,” “cosmetics,” “cosmetic products,” “cosmeceuticals”, “cosmetovigilance,” “prevalence”, and “incidence” linked with Boolean operators such as OR and AND. Additional search was also conducted to identify pertinent studies by examining the reference lists of full-text articles.

4.10.3 Eligibility criteria

The review included studies published in English language that reported the prevalence of adverse events due to various cosmetic products. Articles were excluded if they reported reactions to specific cosmetic products, targeted only a particular adverse reaction, failed to report the prevalence of adverse events, or if the prevalence of events could not be calculated as a percentage of the sample that used cosmetics. Additionally, clinical reports, meta-analyses, systematic reviews, literature reviews, conference abstracts, summary articles, letters to the editor, case reports or case series, and animal studies were excluded. Furthermore, research protocols for which only abstracts were available for analysis, and whose results were not

published or not available in the database, were excluded. Moreover, cosmetics used in the pediatric population were not considered in this review.

4.10.4 Selection of studies and data extraction

Following the predetermined eligibility criteria, two investigators independently screened the titles and abstracts of retrieved papers from the databases. In the next step, full texts of potentially relevant papers were evaluated to identify studies that met the eligibility criteria. Both reviewers separately assessed each study, and a final decision was reached by referring to a senior reviewer regarding the inclusion of each study before the data collection process. Data were extracted from all selected studies using a well-structured data collection form. The extracted data included general characteristics of the studies, such as author's name, year of publication, country of study, participants' age, gender distribution, type of participants, sample size, and prevalence of adverse events. To explore the determinants of adverse events caused by cosmetics, we specifically extracted data from studies that performed bivariate or multivariate analyses and reported their results using adjusted odds ratios (AORs) if found statistically significant.

4.10.5 Quality assessment

Two reviewers independently evaluated the methodological quality of the studies using a critical assessment checklist developed by the Joanna Briggs Institute (JBI) (241). This checklist, consisting of nine questions (Q1-Q9), focused on aspects such as the sampling frame, study subjects, sample size, methods, and statistical analysis. In cases where disagreements arose between the reviewers, a third investigator was consulted for resolution. The total scores on the JBI checklist ranged from 0 to 9. For inclusion in this review, studies with a total score of more than 5, indicating 'Yes' ratings to the checklist questions, were considered.

4.10.6 Synthesis of findings

R software (v. 4.2.2) and package "meta" was used for the analysis. Quantitative synthesis was done utilizing a random-effects model (maximum likelihood estimator - MLE) due to the observed high heterogeneity (I^2 = 100%) among the studies. The

outcomes were visually presented using forest plots, and the pooled prevalence was calculated at a 95% confidence level. To estimate the impact of individual studies on the pooled prevalence, a sensitivity analysis was carried out by systematically excluding one study at a time. Additionally, to further explore regional influences on heterogeneity, a subgroup analysis based on study regions was conducted. Another subgroup analysis based on the type of participants involved in the study was also carried out. The assessment of publication bias was conducted using a visual assessment of funnel plot and Egger's test (242).

4.11 Assessment of knowledge and attitude regarding cosmetic utilization and associated adverse events

4.11.1 Study design and setting

A cross-sectional study was conducted among the general population in Jalandhar, Amritsar and Ludhiana region of Punjab, India. The province of Punjab divides into the three geographical regions Doaba, Majha, and Malwa. From each region, one major city such as Jalandhar, Amritsar, and Ludhiana were selected. This study was conducted from January 2024 to March 2024.

4.11.2 Study population

Participants' selection was done on the basis of pre-defined inclusion and exclusion criteria.

4.11.2.1 Inclusion criteria

a) Residents of Jalandhar, Amritsar and Ludhiana were included in the study irrespective of their nationality and gender.

b) Person who has a habit of using any categories of cosmetic products and who can read/ write either English, Punjabi or Hindi.

c) Age ranging from 18 to 50 years were invited to participate in this study.

d) Willingness to participate in the study by providing signed informed consent form.

4.11.2.2 Exclusion criteria

a) Persons with hearing and sight problems.

4.11.3 Sample size

The number of participants included in this study was decided by a formula $n = Z^2 *P(1-P)/d^2$. This formula was used for calculating the sample size, where n = sample size, Z = 1.96, for 95% confidence interval, d = 5%, degree of precision and P =62.6 %, taken from previous study (237). The sample size was coming out to be 359. To increase the power of the study, total 380 participants was taken.

4.11.4 Data collection

A structured self-administered questionnaire was designed by referring the previously published articles and modified as per the study requirements (55, 237). Designed questionnaire consisted of both open ended and close ended questions. Initially the questionnaire was developed in English and was translated into Hindi and Punjabi. Hindi is the national language of India and Punjabi is the local language of Punjab. The twenty-five-items questionnaire was broadly categorized into three sections; Section A consisted of sociodemographic details of participants such as age, gender, marital status, residence, family monthly income, occupation, education (Q1-Q7), section B consisted of questions related to knowledge regarding cosmetic utilization and adverse events such as what is the first step of facial skincare, which is the appropriate skin type for using cosmetic powders, Which vitamin is commonly found in skincare products and is known for antiaging properties etc. (Q8-Q18) and section C consisted of questions related to attitude regarding cosmetics utilization and adverse events such as use of cosmetics inappropriately can lead to wrinkles, skin darkening, and rashes, quality matters more than price in cosmetics etc. (Q19-Q25). 5-point Likert scale was used to identify the attitude regarding cosmetics utilization and adverse events.

4.11.5 Validation

The content validity of the questionnaire was done by five experts from diverse background comprising of clinician, biostatistician, doctorate academic pharmacists.

All the experts had prior experienced in questionnaire-based study. The content validity of the questionnaire was assessed as per the Lawshee method(238). The content validity index (CVI) of the questionnaire (S-CVI/Ave) was determined by averaging the I-CVIs for each item on the questionnaire. S-CVI/Ave was found to be 0.91. Face validation was done by distributing questionnaire to 20 participants. These 20 questionnaires were not included in the final results. Reliability assessment of the scale was done by calculating Cronbach alpha using SPSS 16. The alpha coefficient for the twenty-five items was found to be 0.737, suggesting that the items are acceptable.

4.11.6 Administration of questionnaire

The questionnaire will be distributed to the public in the different places like schools, colleges, shopping malls, medical stores, general stores, market, hospitals, and park. Convenient sampling method was used to select the study participants. Purpose of the study were explained to all the participants. Informed consent was taken from all the participants before filling the questionnaire. A face-to-face interview was conducted by investigator in case of illiterate participants. The questionnaires were evaluated for their completeness and only the completed questionnaires were taken for the final analysis.

4.11.7 Ethical consideration

The study protocol was approved by the Institutional Ethics Committee of Lovely Professional University (Ref. no.: LPU/IEC-LPU/2023/1/25). Written informed consent was taken from the all the participants.

4.11.8 Data analysis

The collected data was analyzed using SPSS (Statistical Packages for Social Sciences) software version 16. Descriptive statistics (number and percentage) were used to summarize demographic details, knowledge and attitude regarding cosmetic utilization and adverse events. Participants' knowledge was assessed by assigning a score of 1 for correct answers and 0 for incorrect and each participant's overall knowledge scores calculated. The attitude score was computed by aggregating the

ratings (ranging from 1 to 5) provided by each participant for every question. Bloom cut off point used to find out the high knowledge score and positive attitude of the participants (243, 244). Descriptive statistics (number and percentage) were used to summarize demographic characteristics, knowledge and attitude of participants regarding cosmetic utilization and associated adverse events.

CHAPTER - 5

5 Results and Discussion

5.1 Sociodemographic characteristics

The ratio of male and female was found to be 2:3. Mean (±SD) age of the participant was 27.43 (±10.2) years. The majority of participants (63.2%) were single, and 12.2% of participants reported having a history of food and drug allergy. Majority of the participants (76.5%) belongs from urban area and about half (51%) of participants were graduate and higher degree education. Socio-demographic details of the participants are given in Table 6.

Table 6. Sociodemographic characteristics of the participant

Variables	Male n (%) (N=160)	Female n (%) (N=240)	Total n (%) (N=400)
Age in years			
15-25	113 (70.6)	121 (50.4)	234 (58.5)
26-36	31 (19.3)	53 (22)	84 (21)
37-47	14 (8.7)	43 (17.9)	57 (14.2)
≥48	2 (1.2)	23 (9.5)	25 (6.2)
Marital status			
Single	125 (78.1)	128 (53.3)	253 (63.2)
Married	35 (21.8)	110 (45.8)	145 (36.25)
Divorced	0 (0)	1 (0.4)	1 (0.2)
Widow	0 (0)	1 (0.4)	1 (0.25)
Drug and food allergy			
Yes	13 (8.1)	36 (15)	49 (12.2)
No	147 (91.8)	204 (85)	351 (87.7)
Family history of allergy			
Yes	15 (9.3)	34 (14.6)	49 (12.2)
No	145 (90.6)	206 (85.8)	351 (87.7)
Residence			
Urban	126 (78.7)	180 (75)	306 (76.5)
Rural	34 (21.2)	60 (25)	94 (23.5)
Monthly income (INR)			
<10000	85 (53.1)	136 (56.6)	221 (55.2)
10001-20000	29 (18.1)	33 (13.7)	62 (15.55)
20001-40000	17 (10.6)	24 (10)	41 (10.2)
40001-60000	9 (5.6)	22 (9.1)	31 (7.7)
>60000	20 (12.5)	25 (10.4)	45(11.3)
Educational status			
Illiterate	3 (1.8)	6 (2.5)	9 (2.2)

Primary	7 (4.3)	12 (5)	19 (4.7)
10^{th}	30 (18.7)	38 (15.8)	68 (17)
12^{th}	45 (28.1)	55 (22.9)	100 (25)
Graduate & Higher	75 (46.8)	129 (53.7)	204 (51)
Occupation			
Student	77 (48.1)	101 (42)	178 (44.5)
Unemployed	15 (9.3)	5 (2)	20 (5)
Homemaker	1 (0.63)	49 (20.4)	50 (12.5)
Government employee	7 (4.3)	26 (10.8)	33 (8.2)
Private job	43 (26.8)	47 (19.5)	90 (22.5)
Business	17 (10.6)	12 (5)	29 (7.2)

5.2 Cosmetic utilization behaviors

More than half of the participants (54.7%) used 1–2 cosmetics per day and nearly fifty percent (n = 49%) used cosmetics twice daily. A significant proportion of participants (35.2%) added water and other agents to their cosmetics and more than half of the study participants (58.7%) shared cosmetics with friends or family members. The most popular means of acquiring cosmetics were a mix of local shops, drug stores, shopping centers, cosmetics stores, and online. A total of 213 (53.2%) participants read the instructions and only [(n = 118) 29.5%] conducted an allergy test before applying cosmetics. More than half of the individuals [(n = 226) 56.5%] admitted that they frequently switched cosmetic brands. The vast majority of consumers [(n = 341) 85.2%] said they check the date of expiration before using a product. The most commonly used cosmetics products by participants were makeup and personal care products (Fig. 2). Details of cosmetic utilization behavior and safety measures taken by cosmetics users are given in Table 7.

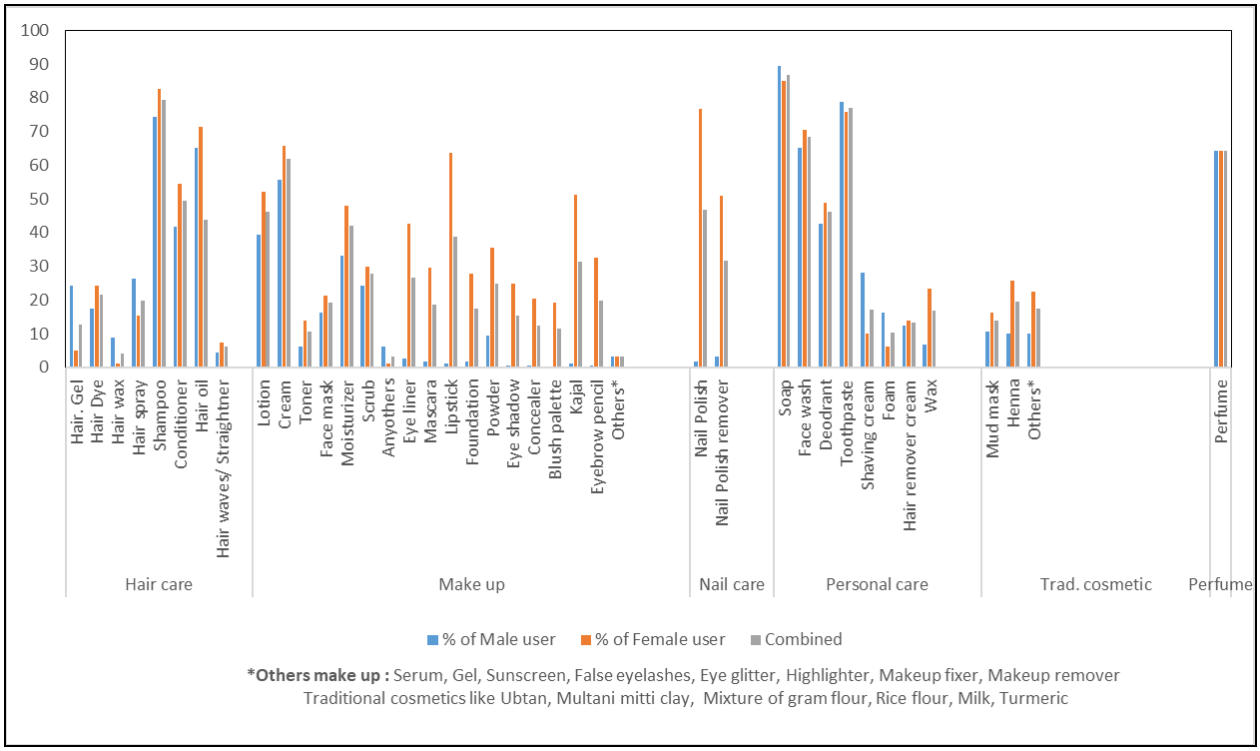

Figure 2. Types of cosmetics used on the basis of gender

Table 7. Cosmetic use behaviors

Variables	Male n (%) (N=160)	Female n (%) (N=240)	Total n (%) (N=400)
Number of cosmetics used per day			
1-2	97 (60.6)	122 (50.8)	219 (54.7)
3-5	41 (25.6)	78 (32.5)	119 (29.7)
6-8	1 (0.63)	15 (6.2)	16 (4)
>8	21 (13.1)	25 (10.4)	46 (11.5)
Number of times used per day			
1	66 (41.2)	78 (32.5)	144 (36)
2	74 (46.2)	122 (50.8)	196 (49)
3	13 (8.1)	24 (10)	37 (9.2)
>3	7 (4.3)	16 (6.6)	23 (5.7)
Adding water/other agent in cosmetic	60 (37.5)	81 (33.7)	141 (35.2)
Sharing cosmetic with friends/family	88 (55)	147 (61.2)	235 (58.7)
Stored as mentioned on the label	128 (80)	191 (79.5)	319 (79.7)
Source of cosmetics purchasing			
Drug store	8 (5)	13 (5.4)	21 (5.2)
Shopping mall	18 (11.2)	36 (15)	54 (13.5)
Local shop	33 (20.6)	35 (14.5)	68 (17)
Cosmetic store	8 (5)	35 (14.5)	43 (10.7)
Online	30 (18.7)	37 (15.4)	67 (16.7)
Mixed	63 (39.3)	84 (35)	147 (36.7)
Read instruction in the label			
Yes	80 (50)	133 (55.4)	213 (53.2)
No	34 (21.2)	48 (20)	82 (20.5)
Sometimes	46 (28.7)	59 (24.5)	105 (26.2)

Testing of allergy			
Yes	29 (18.1)	89 (37)	118 (29.5)
No	109 (68.1)	122 (50.8)	231 (57.7)
Do not know	22 (13.7)	29 (12.0)	51 (12.7)
Change cosmetic brand			
Yes	89 (55.6)	137 (57.0)	226 (56.5)
No	71 (44.3)	103 (42.9)	174 (43.5)
Check expiry date			
Yes	137 (85.6)	204 (85)	341 (85.2)
No	23 (14.3)	36 (15)	59 (14.7)

5.3 Cosmetics associated adverse events

A total of 132 of participants experienced one or more adverse events within the preceding two years. The prevalence of cosmetics induced adverse event was found to be 33%. A total of 347 adverse events experienced by 132 individuals. Most commonly reported adverse events were itching (frequency = 58), redness (frequency = 59) and pimples (frequency = 42). Details of the other different adverse events are shown in Fig. 3. Majority of reported adverse events were related to skin care products 64 (46%), followed by hair care 39 (28.1%) and personal care 24 (17.3%) products. The majority of the participants (69.7%) managed the adverse events by cessation of use of products, 22.7% consulted physicians, 20.4% used medication and 11.4% followed some other methods. Individuals who were unaware that performing an allergy test before using cosmetics were more likely to have adverse events (AOR 1.99; 95% CI 1.04–3.80). Other variables like age, residence, marital status, family history of allergy to food & medicine, income, cosmetics used per day, frequency of cosmetic used, mixing of water, sharing of cosmetics, instruction didn't show statistically significant association with the adverse events. Predictors of adverse events are presented in Table 8.

5.4 Causality assessment

Causality assessment of cosmetic induce adverse event was done by using COLIPA scale. Causality assessment reveals that majority of the adverse events (frequency =260) were categorized into not clearly attributable. Details of causal association of AEs are presented in Table 9.

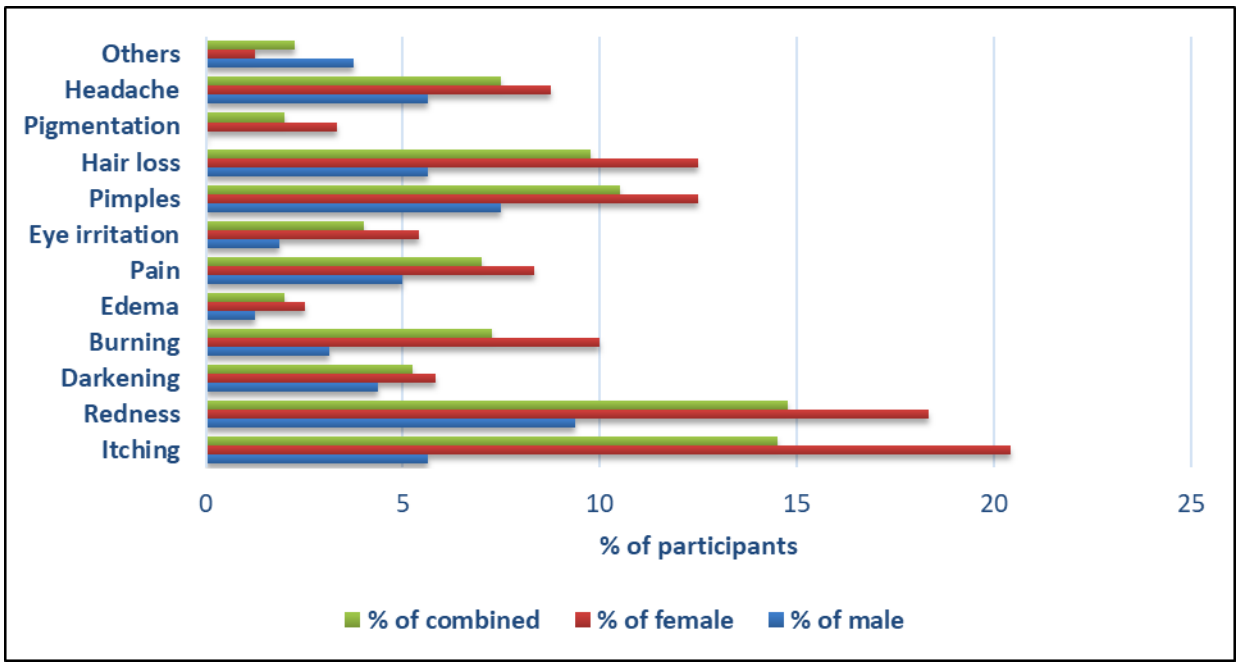

Figure 3. Cosmetics associated adverse events

Table 8. Predictor of adverse events

Variables	Total no of participants	Patients with AEs		Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)
		Yes	No		
Gender					
Male	160	41	119	1	1
Female	240	91	149	1.53 (0.91-2.57)	1.77 (1.14-2.75)*
Personal history of drug & food allergy					
Yes	49	36	13	1	1
No	351	96	255	0.19(0.09-0.43)*	0.13(0.06-0.26)*
Family history of drug & food allergy					
Yes	49	27	22	1	1
No	351	105	246	0.75 (0.35-1.62)	0.34 (0.18-0.63)*
Residence					
Rural	94	25	69	1	1
Urban	306	107	199	0.57 (0.30-1.06)	0.67 (0.40-1.12)
Education					
Illiterate	9	4	5	1	1
Primary	19	8	11	0.40 (0.09-1.75)	0.54 (0.14-2.10)
10th	68	28	40	0.33 (0.11-0.98)	0.60 (0.23-1.56)
12th	100	30	70	0.53 (0.27-1.06)	0.62 (0.35-1.10)
Graduate & Higher	214	62	142	0.89 (0.48-1.66)	1.01 (0.60-1.71)
Expiry date					
No	59	13	46	1	1
Yes	341	119	222	1.49 (0.73-3.03)	1.89 (0.98-3.65)*
Changing cosmetic brands frequently					
Yes	226	89	137	1	1
No	174	43	131	0.61 (0.37-1.02)	0.50 (0.32-0.78)*
Performed allergy test					
Yes	118	60	58	1	1
No	231	53	178	0.71 (0.32-1.56)	0.57 (0.29-1.12)
Do not know	51	19	32	2.22 (1.0-4.68)	1.99 (1.04- 3.80)*

Table 9. Causality assessment

Adverse events	**Frequency**	**Causality assessment**	
		Likely	Not Clearly attributable
Itching	58	15	43
Redness	59	12	47
Darkening	21	6	15
Burning	29	9	20
Edema	8	3	5
Pain	28	10	18
Eye irritation	16	2	14
Pimples	42	8	34
Hair loss	39	11	28
Pigmentation	8	1	7
Headache	30	9	21
Others	9	1	8

5.5 Study screening

The database search originally identified 1,398 potentially relevant citations. Additionally, a comprehensive search of the reference lists of potentially eligible articles found 10 more relevant articles. After eliminating duplicates, 1,306 citations remained for subsequent evaluation. During the screening of titles and abstracts, 1,259 articles were excluded as they did not meet the predefined criteria. Subsequently, a full-text examination of 47 studies led to the exclusion of 24 papers for various reasons. Ultimately, 23 studies that aligned with the inclusion criteria were considered for inclusion in this study. An adapted PRISMA diagram (**Figure 4**) was used to illustrate the study selection process.

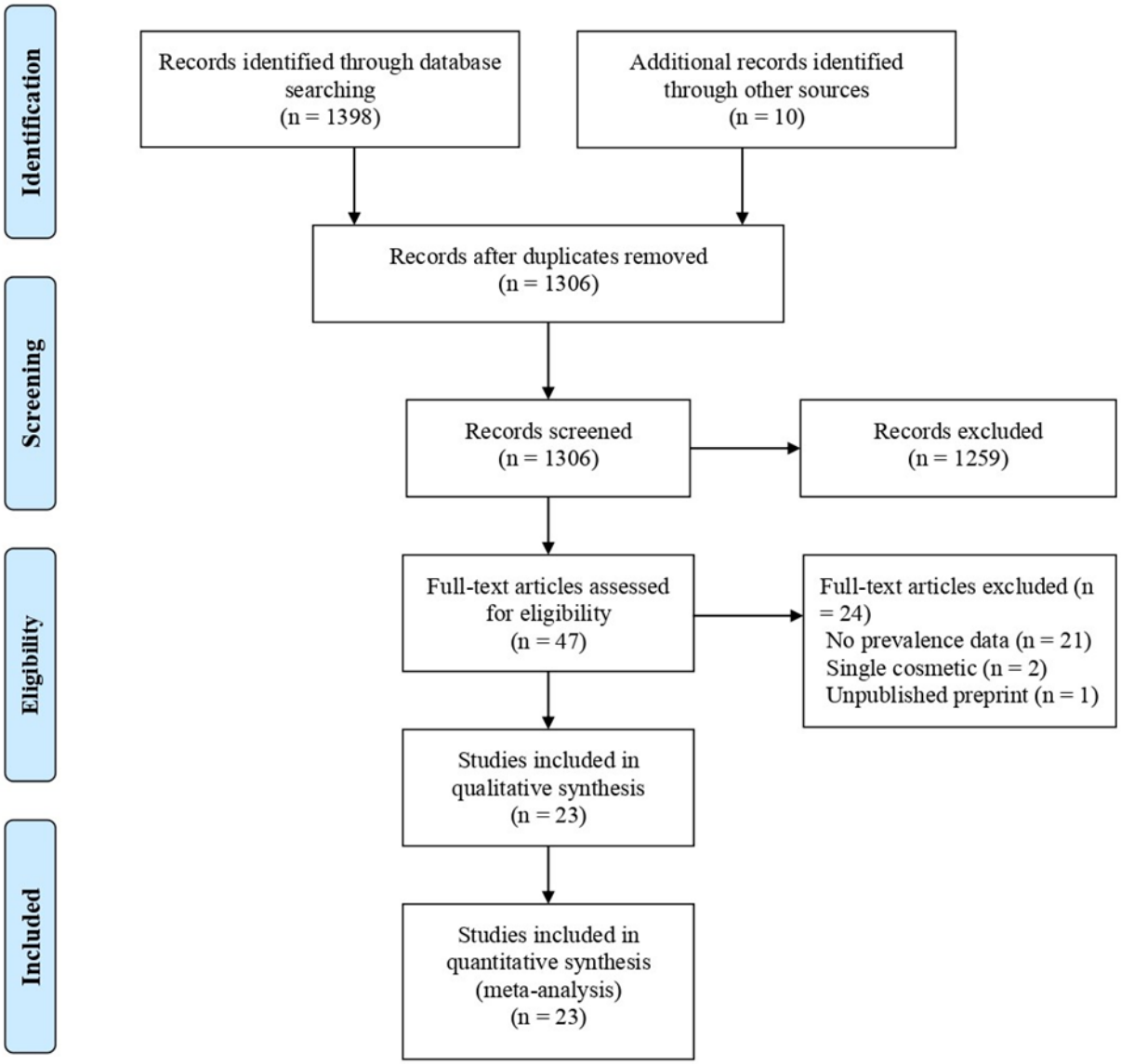

Figure 4. PRISMA flow diagram showing the process of records selection

5.6 Characteristics of included studies

In this analysis, 23 papers published between 1987 (245) and 2023 (50, 53, 59, 246) were included to examine the prevalence of adverse events resulting from cosmetic use. These studies, predominantly conducted in community settings, presented sample sizes ranging from 70 (225) to 3,474(56) , collectively encompassing 13,872 cosmetic users. Most participants were of younger ages (<30 years). The gender distribution, based on 22 studies (one lacking gender specification), revealed a predominantly female participant base (82.5%). The prevalence of adverse events associated with cosmetics within the included studies exhibited a considerable range, from 16.1% (232) to 85.1% (223). The characteristics of these studies are outlined in **Table 10**.

Table 10. Characteristics of included studies

Author, year, reference	Country of study	Type of participants	Sample size	Mean age/age range (years)	Gender distribution	Prevalence (%)
Addis et al., 2023, (53)	Ethiopia	Students	338	20.4 ± 3.5	F: 338 (100%) M: 0	65.1
Sniepiene et al., 2019, (229)	Lithuania	General population	336	NS	F: 336 (100%) M: 0	80.4
Bilal et al., 2017,(54)	Ethiopia	General population	559	18-40	F: 424 (76%) M:135 (24%)	61.2
Hadi et al., 2020, (247)	Malaysia	General population	552	20-59	F: 445 (80.6%) M: 107 (19.4%)	29.0
Di Giovanni et al., 2006, (56)	Italy	General population	3474	NS	F: 2688 (77.4%) M: 786 (22.6%)	24.4
El Emam et al., 2022, (57)	Egypt	Students	691	NS	F: 691 (100%) M: 0	84.7
Lucca et al., 2020, (233)	Saudi Arabia	General population	425	10-67	F: 316 (74.3%) M: 109 (25.7%)	50.6

Shaaban et al., 2020, (232)	Saudi Arabia	General population	709	NS	F: 709 (100%) M: 0	16.1
Getachew et al., 2018, (228)	Ethiopia	Institute employees	310	NS	F: 310 (100%) M: 0	19.0
Dibaba et al., 2013, (221)	Ethiopia	Students	710	19-24	F: 710 (100%) M: 0	18.4
Meharie et al., 2015, (224)	Ethiopia	Students	214	19-26	F: 214 (100%) M: 0	31.8
De Groot et al., 1987, (245)	Netherlands	General population	1609	33-64	F: 771 (47.9%) M: 838 (52.1%)	12.2
De Groot et al., 1988,(248)	Netherlands	Beauty salon clients	982	14-78	F: 982 (100%) M: 0	25.9
Shrestha et al., 2016, (225)	Nepal	Students	70	17.6 ± 1.1	F: 70 (100%) M: 0	34.3
Al-Ghamdi et al., 2020, (249)	Saudi Arabia	Students	401	NS	F: 410 (100%) M: 0	37.9
Girish et al., 2022, (250)	India	Students	202	NS	F: 145 (71.8%) M: 57 (28.2%)	35.1
Kureh et al., 2020, (231)	Tanzania	Students	112	NS	F: 71 (63.4%) M: 41 (36.6%)	58.0
Kumari et al., 2023, (50)	India	General population	400	27.4 ± 10.2	F: 240 (60%) M: 160 (40%)	33.0
Nayak et al., 2023a, (251)	India	General population	791	18-60	F: 791 (100%) M: 0	38.2
Nayak et al., 2023b, (246)	India	Patients	395	18-60	F: 395 (100%) M: 0	44.1
Huf et al., 2013, (222)	Brazil	Institute employees	200	37.8 ± 8.2	NS	38.0
Shiraz et al., 2019, (252)	India	General population	150	25.0 ± 7.0	F:150 (100%) M: 0	39.3
Binega et al., 2014, (223)	Ethiopia	Students	242	16-30	F: 73 (30.2%) M: 169 (69.8%)	85.1

*NS not specified/not specified clearly; F female; M male

5.7 Quality assessment

Each of the included studies received a grade of 'Yes,' exceeding the threshold set at 5, indicating their suitability for inclusion in the study due to their strong methodological quality. The results of the evaluation of methodological quality is mentioned in Table 11.

Table 11. Quality assessment of included studies using JBI Critical Appraisal Checklist

Study ID	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Total score
Addis et al., 2023	Yes	Yes	Yes	Yes	Yes	U	Yes	Yes	Yes	8
Sniepiene et al., 2019	Yes	No	Yes	Yes	Yes	U	Yes	Yes	U	6
Bilal et al., 2017	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Hadi et al., 2020	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Di Giovanni et al., 2006	Yes	Yes	Yes	Yes	Yes	U	Yes	Yes	Yes	8
El Emam et al., 2022	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Lucca et al., 2020	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Shaaban et al., 2020	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Getachew et al., 2018	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Dibaba et al., 2013	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Meharie et al., 2015	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9

De Groot et al., 1987	Yes	Yes	Yes	Yes	Yes	U	Yes	Yes	Yes	8
De Groot et al., 1988	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	7
Shrestha et al., 2016	Yes	Yes	No	Yes	Yes	U	Yes	Yes	Yes	7
Al-Ghamdi et al., 2020	Yes	Yes	Yes	Yes	Yes	U	Yes	U	Yes	7
Girish et al., 2022	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8
Kureh et al., 2020	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8
Kumari et al., 2023	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Nayak et al., 2023a	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Nayak et al., 2023b	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	9
Huf et al., 2013	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	8
Shiraz et al., 2019	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	6
Binega et al., 2014	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	8

*U unclear

5.8 Prevalence of cosmetic-induced adverse events

The pooled prevalence of cosmetic induced adverse events among cosmetic users was found to be 41.1% (95% CI: 31.7; 51.1). However, significant heterogeneity was observed among the studies (I^2 = 99%; τ^2 = 0.9760; p = 0). The forest plot showing the prevalence is depicted in **Figure 5.**

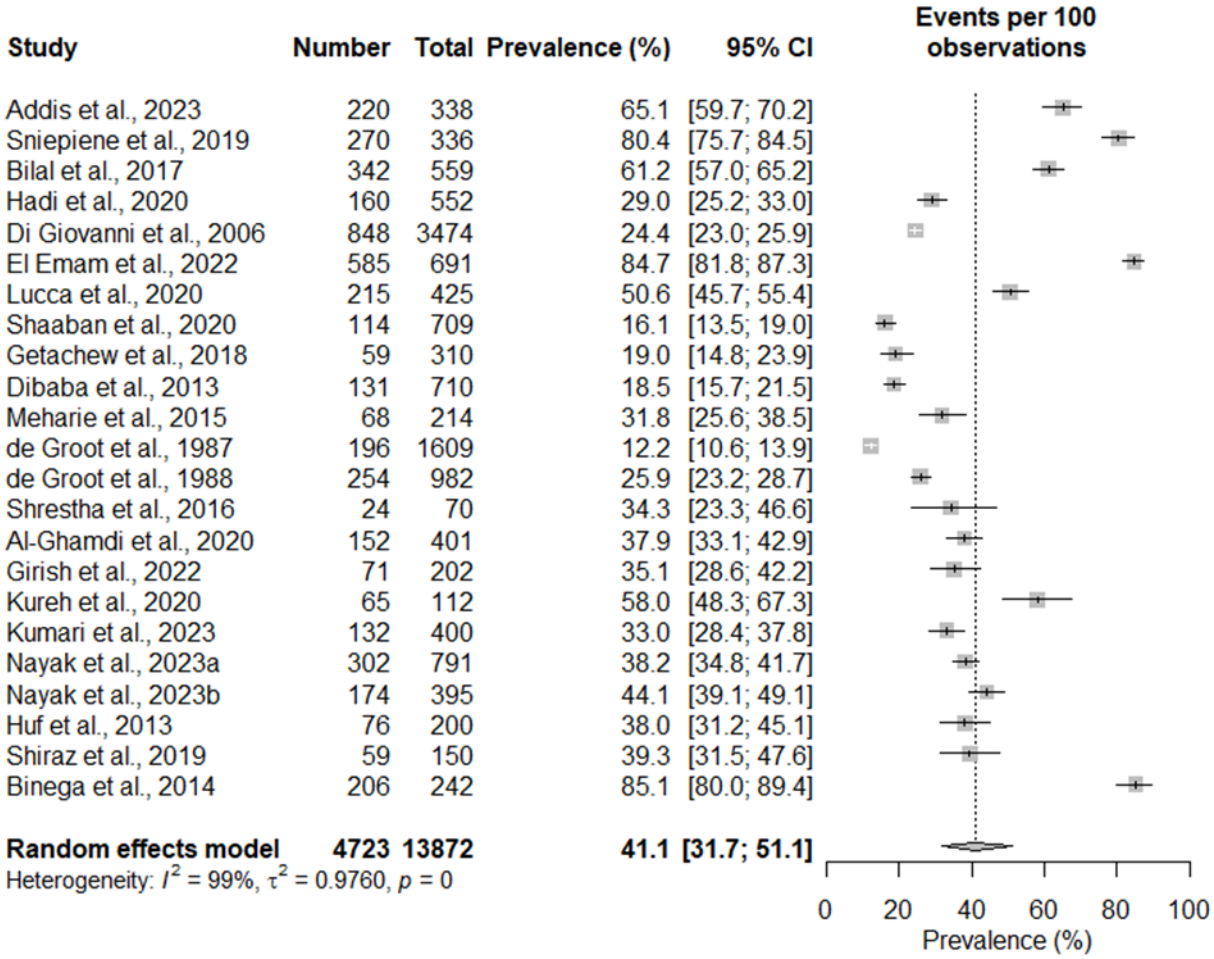

Figure 5. The overall global prevalence of cosmetic-induced adverse events

5.9 Subgroup analysis and sensitivity analysis

Subgroup analysis based on the region of study found that the African continent had the highest prevalence at 53.6% (95% CI: 33.5; 72.6), followed by South America at 38% (95% CI: 31.2; 45.1), Asia at 35.0% (95% CI: 29.2; 41.4), and Europe having the lowest prevalence of 33.4% (95% CI: 12.7; 63.3). However, the subgroup difference test did not demonstrate significant regional variations in the prevalence of cosmetic-induced adverse events ($p = 0.38$) (**Figure 6**). When subgrouping the studies based on the types of participants recruited for the assessment, it was observed that students had the highest rate of adverse events induced by cosmetics (51.1%; 95% CI: 34.1; 67.9), while studies conducted in the general population had a prevalence rate of 36.8% (95% CI: 24.4; 51.1), and the difference in the subgroup was also found to be statistically significant ($p < 0.01$) (**Figure 7**).

The results of the sensitivity analysis confirmed that removing individual studies did not considerably affect the pooled prevalence of adverse reactions caused by using cosmetics.

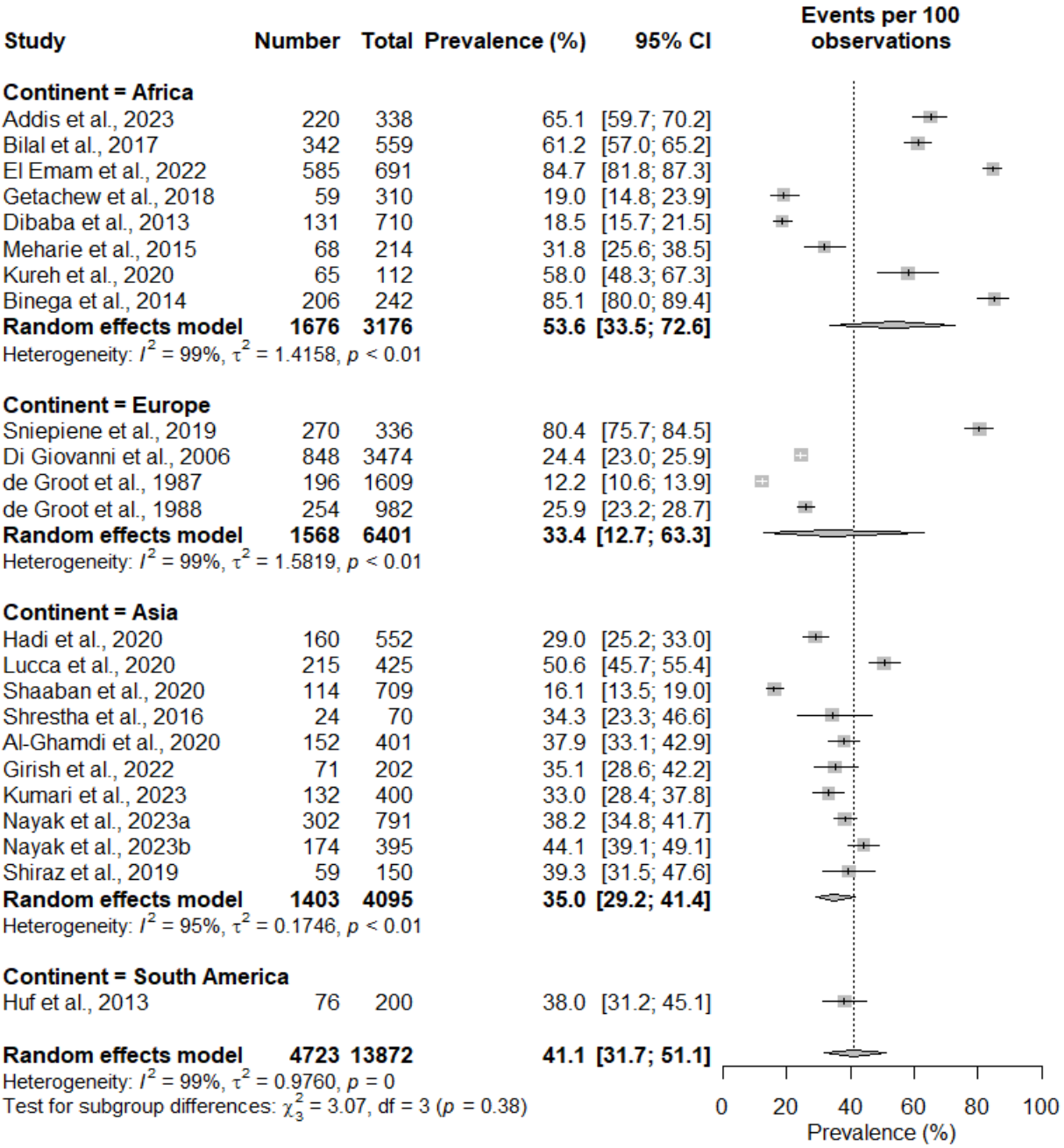

Figure 6. Subgroup anaysis based on study region

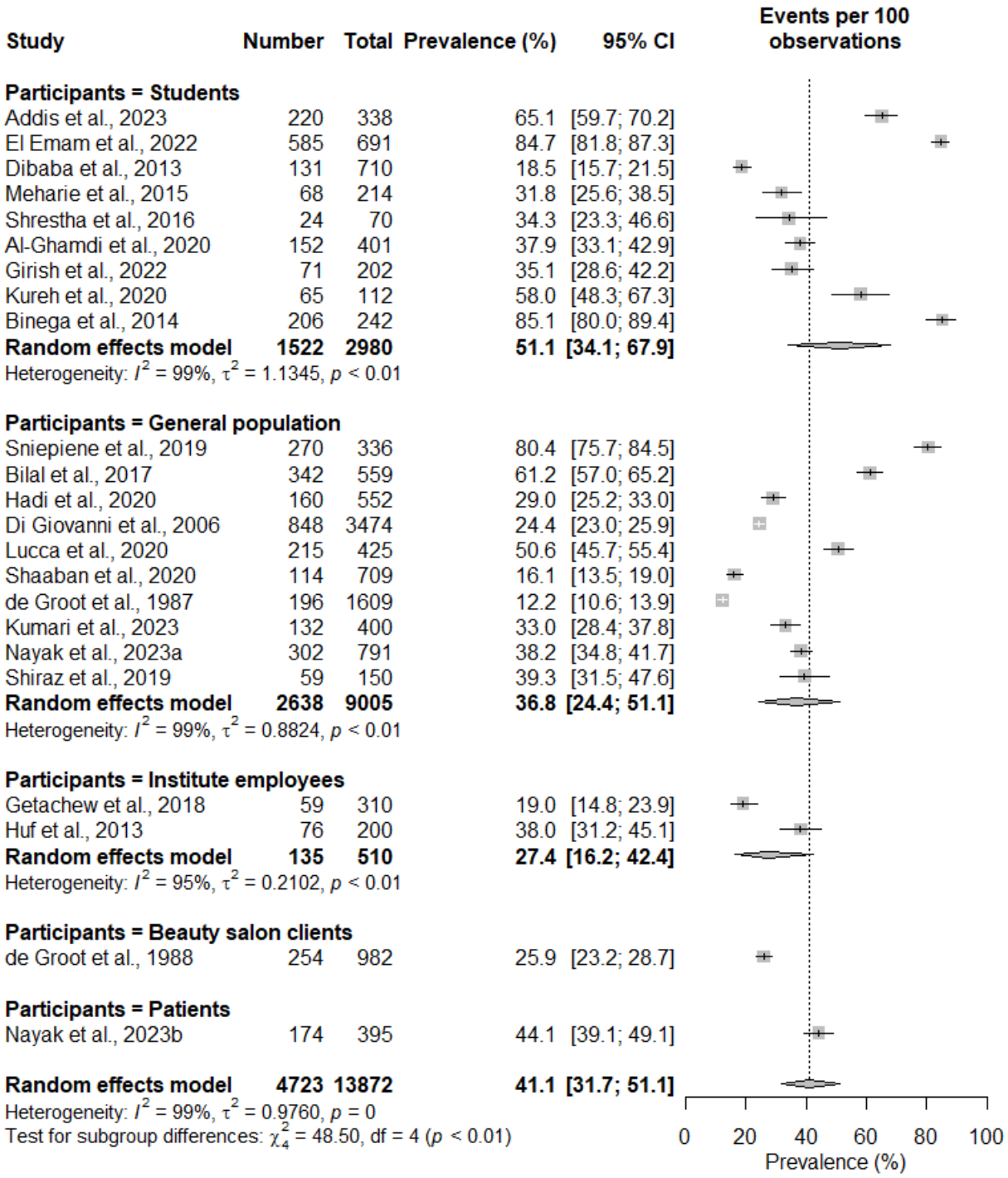

Figure 7. Subgroup analysis based on types of participants

5.10 Publication bias

The visual inspection of funnel plot found that the included studies did not exhibit complete symmetry, indicating the presence of publication bias (**Figure 8**), and this was further confirmed by the result of Egger's test ($p = 0.041$).

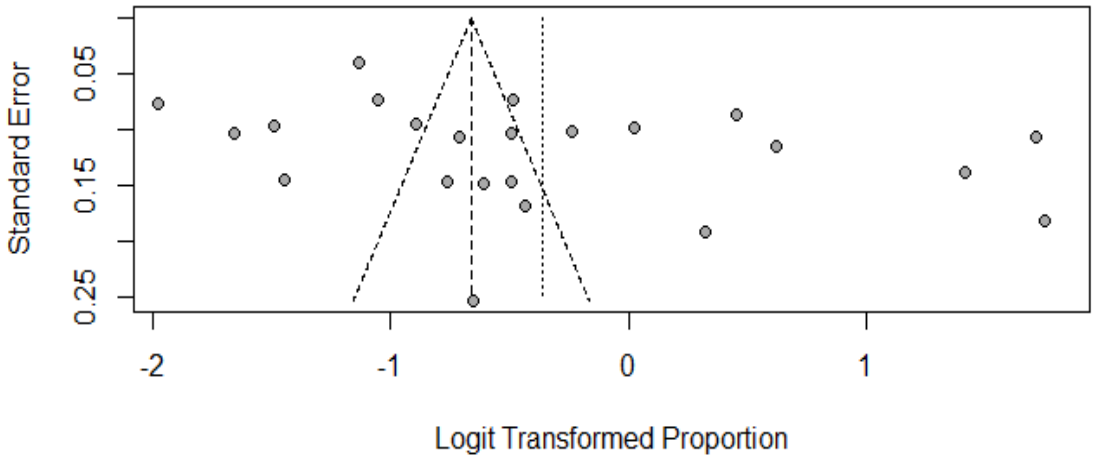

Figure 8. Funnel plot for assessing publication bias

5.11 Determinants of cosmetic-induced adverse events

Several factors have been identified as contributors to the increased occurrence of cosmetic-induced adverse events. Habits such as the daily use of multiple cosmetics(53, 54), frequent application(54), and a personal or family history of allergies (50, 233) to specific medications and foods are among these contributing factors. Furthermore, prolonged intervals without washing applied cosmetics (53) have been found to be substantially associated with a higher occurrence of adverse events. Urban residence (53), higher educational status (54), and good financial condition (53, 228) were additional factors correlated with a high susceptibility to adverse events. Moreover, the data indicated that individuals of the female gender (50) and younger age (54) were more prone to both the use of cosmetics and subsequently exhibiting adverse reactions to them. Additionally, the act of mixing different cosmetic products(54, 233) and combining them with saliva or water (54) were identified as significant determinants contributing to the occurrence of cosmetic-induced adverse events. The various determinants of adverse events reported in the included studies are presented in **Table 12**.

Table 12. Factors associated with cosmetic-induced adverse events

Author, reference	Risk factors	AOR (95% CI)	*p*-value
Addis et al., (53)	Previous urban residence	2.43 (1.06–5.52)	0.034
	≥ 500 ETB monthly pocket money	2.76 (1.26–6.05)	0.011
	Using 3–5 cosmetics/day	7.41 (2.29–24.03)	0.001
	Practice of label-reading	2.63 (1.20–5.88)	0.016
	Cosmetics left unwashed for		
	1 day	9.4 (3.18–60.7)	0.001
	4–5 days	6.73 (1.5–40.5)	0.02
	> 5 days	10.12 (4.3–35.8)	0.001
Bilal et al., (54)	Younger age (16–20 years)	1.69 (1.11–2.94)	< 0.05
	Higher educational status (college/university)	2.77 (1.11–7.00)	< 0.05
	Applying cosmetics daily	1.67 (1.01–2.78)	< 0.05
	Number of cosmetics used/day		
	2–4 cosmetics/day	1.46 (1.21–1.67)	< 0.05
	5–6 cosmetics/day	1.64 (1.10–6.28)	< 0.05
	> 6 cosmetics/day	2.56 (1.55–4.26)	< 0.05
	Frequency of applying cosmetics/day		
	2 times/day	2.27 (1.21–4.24)	< 0.05
	3 times/day	1.82 (1.00–3.39)	< 0.05
	> 3 times/day	1.92 (1.03–3.57)	< 0.05
	Way of using cosmetics		
	mixing them as such	1.98 (1.18–3.20)	< 0.05
	mixing them with water or saliva	5.83 (2.64–12.87)	< 0.05
Lucca et al., (233)	Allergic to medication	3.9 (1.66–9.17)	0.000
	Family history of allergy	1.91 (1.24–2.95)	0.000
	Mixing cosmetics	1.70 (1.07–2.68)	0.001

Getachew et al., (228)	Monthly income		
	1000–3000 ETB	3.4 (1.4–8.4)	0.011
	≥ 3000 ETB	4.7 (1.8–12.2)	0.015
	Using traditional cosmetics	4.5 (2.1–9.6)	0.001
Kumari et al., (50)	Female gender	1.77 (1.14–2.75)	< 0.05
	Personal history of drug and food allergy	7.69 (3.85–16.67)	< 0.05
	Family history of drug and food allergy	2.94 (1.59–5.55)	< 0.05
	Checking expiry date of products	1.89 (0.98–3.65)	< 0.05
	Frequently changing cosmetic brands	2.00 (1.28–3.12)	< 0.05
	No knowledge of allergy test	1.99 (1.04–3.80)	< 0.05

*AOR adjusted odds ratio; ETB Ethiopian Birr

5.12 Sociodemographic characteristics

The study enrolled a total of 380 participants, with 80.6% falling within the age range of 18-28 years. The majority of participants were female (52.3%), and a significant proportion were unmarried (57.1%). Additionally, 30.4% reported a monthly income >60000 Rs, while 49.9% held a graduate or higher degree and 43.3% currently enrolled as students. Sociodemographic characteristics of the participants is given in Table 13**.**

Table 13. Sociodemographic characteristics of the participants

Variables	N (%)
Age	
18-28	231 (80.6)
29-39	107 (28.1)
40- 50	42 (11)
Gender	
Male	181 (47.6)
Female	199 (52.3)
Transgender	0 (0)
Marital status	
Single	217 (57.1)
Married	159 (41.8)
Divorced	3 (0.8)
Widow	1 (0.3)
Residence	
Urban	278 (73.2)
Rural	102 (26.8)
Family Monthly income (Rs)	
<10000	34 (8.9)
10001- 20000	39 (10.2)
20001- 40000	95 (24.9)
40001- 60000	96 (25.2)
>60,000	116 (30.4)
Educational status	
Illiterate	6 (1.6)
Primary	23 (6)
10th	29 (7.6)
12th	132 (34.6)
Graduate & Higher	190 (49.9)

Occupation	
Student	108 (28.3)
Unemployed	9 (2.4)
House maker	37 (9.7)
Govt. Employee	18 (4.7)
Private Job	165 (43.3)
Business	43 (11.3)

5.13 Knowledge of the participants regarding cosmetics utilization and adverse events

The mean (± SD) score of participants' knowledge about cosmetic utilization and adverse events was 4.72 ± 2.41. The majority of participants (51.7%) were aware that cleanser milk is the initial step in facial skincare, while 47.2% possessed the correct understanding that cosmetic powder is most suitable for oily skin types. Likewise, 59.3% accurately identified vitamin C as a common ingredient in skincare products known for its anti-aging properties. Additionally, 59.8% correctly stated that sunscreen should be applied 15-30 minutes prior to sun exposure. 43.3% correctly answered petroleum jelly is main ingredients in most lip balm that help moisturize the lip. Moreover, 34.9 knew deep mask is an appropriate conditioner to use after hair dyeing. However, 43.6% answered dandruff is the most common side effect of hair dyes. Only 26% participants knew that heavy metal is when present in elevated levels in cosmetics can lead to toxicities with prolonged use. More than half of the participants (65.6%) answered that sunscreen help in reducing the risk of skin cancer. Very less (11%) participants knew that fragrances in perfumes is the most common cause of cosmetic-induced skin allergy. Similarly, only 28.6% were correct that oil based cosmetics is most likely to have side effects on the skin. Further details regarding the frequency distribution of participants' knowledge concerning cosmetic utilization and adverse events are provided in the accompanying Table 14.

Table 14. Frequency distribution of participant's knowledge regarding cosmetics utilization and adverse events

Questions	Correct N (%)	Incorrect/do not know N (%)	Correct answer
What is the first step in facial skincare?	197 (51.7)	183 (48)	Cleanser Milk
Which is the appropriate skin type for using cosmetic powders?	180 (47.2)	200 (52.5)	Oily skin
Which vitamin is commonly found in skincare products and is known for antiaging properties?	226 (59.3)	154 (40.4)	Vitamin C
When should sunscreen be applied before sun exposure?	228 (59.8)	152 (39.9)	15-30 minutes before sun exposure
What is the main ingredient in most lip balm that help moisturize the lip?	165 (43.3)	215 (56.4)	Petroleum jelly
What is an appropriate conditioner to use after hair dyeing?	133 (34.9)	247 (64.8)	Deep mask
What is the most common side effect of hair dyes?	166 (43.6)	214 (56.2)	Dandruff
Which metal, when present in elevated levels in cosmetics can lead to toxicities with prolonged use.	99 (26)	281 (73.8)	Heavy metal
Which cosmetics help in reducing the risk of skin cancer?	250 (65.6)	130 (34.1)	Sunscreen
What is the most common cause of cosmetic-induced skin allergy?	42 (11)	338 (88.7)	Fragrances in perfumes
Which type of cosmetics is most likely to have side effects on the skin?	109 (28.6)	271 (71.1)	Oil based cosmetics

5.14 Attitude of the participants regarding cosmetics utilization and adverse events

The participants' attitudes toward cosmetic utilization and adverse events were assessed, yielding a mean (± SD) score of 26.09 ± 3.91. Notably, less than half of the participants (42.5%) strongly agreed that inappropriate cosmetic use could result in adverse effects such as wrinkles, skin darkening, and rashes. Conversely, a majority (54.3%) strongly favored prioritizing quality over price when selecting cosmetics. However, confidence in the safety of cosmetics made with organic herbal ingredients was less prevalent, with only 25.2% of participants strongly agreeing on their safety and health benefits. Additionally, a minority (13.4%) held the belief that tattoos could potentially lead to cancer. Concerns about adverse effects extended to hair care products, as 23.1% strongly agreed that chemical hair dyes and bleaching could cause grey hair. On preventive measures, only 12.1% acknowledged the importance of beginning sunscreen use at a young age. Conversely, a notable percentage (31.2%) believed that water is commonly used to remove makeup. Details of frequency of attitude of the participants regarding cosmetics utilization and adverse events were discussed in Table 15.

Table 15. Frequency distribution of participant's attitude regarding cosmetics utilization and adverse events

Questions	Strongly agree N (%)	Agree N (%)	No idea N (%)	Disagree N (%)	Strongly disagree N (%)
Use of cosmetics inappropriately can lead to wrinkles, skin darkening, and rashes.	162 (42.5)	142 (37.3)	37 (9.7)	20 (5.2)	19 (5)
Quality matters more than price in cosmetics.	207 (54.3)	118 (31)	33 (8.7)	6 (1.6)	16 (4.2)
Are cosmetics made with organic herbal ingredients safer and healthier?	96 (25.2)	166 (43.6)	71 (18.6)	35 (9.2)	12 (3.1)
Can a tattoo cause cancer?	51 (13.4)	137 (36)	105 (27.6)	59 (15.5)	28 (7.3)
Grey hair could be a side effect of chemical hair dyes and bleaching.	88 (23.1)	157 (41.2)	91 (23.9)	32 (8.4)	12 (3.1)
It is important to start using sunscreen at a young age.	46 (12.1)	133 (34.9)	108 (28.3)	70 (18.4)	23 (6)
Usually, water is used to remove makeup.	119 (31.2)	127 (33.3)	39 (10.2)	51 (13.4)	44 (11.5)

5.15 Comparison of knowledge and attitude scores among different demographic variables

Only 5.8% the participants had high knowledge and 41.7% had positive attitude. Details is given in table 16. High levels of knowledge were observed within the younger demographic (aged 18-28), alongside a similarly elevated prevalence of positive attitudes within the same age bracket. Furthermore, females exhibited higher levels of both knowledge and positive attitudes. Similarly, unmarried individuals, students, and those possessing higher educational qualifications demonstrated higher knowledge scores. The details of comparison of knowledge and attitude among different demographic variables is given in Table 17 and 18.

Table 16. Categorization of knowledge and attitude scores based on Bloom's criteria

	Category	Score	N (%)
Knowledge	High	9-11(80%-100%)	22 (5.8)
	Moderate	6-8 (60%-79%)	130 (34.1)
	Low	< 6 (< 60%)	228 (59.8)
Total			380 (100)
Attitude	Positive	28-35 (80%-100%)	159 (41.7)
	Neutral	21-27 (60%-79%)	193 (50.7)
	Negative	< 20 (< 60%)	28 (7.3)
Total			380 (100)

Table 17. Comparison of knowledge among different demographic variables

Variables	**High Knowledge (N=22)**	**Moderate Knowledge (N=130)**	**Low Knowledge (N=228)**	**Total (N=380)**
Age				
18-28	14(63.6%)	91(70%)	126(55.2%)	231(60.7%)
29-39	7(31.8%)	30(23%)	70(30.7%)	107(28.1%)
40- 50	1(4.5%)	9(6.9%)	32(14%)	42(11%)
Gender				
Male	10(45.4%)	45(34.6%)	126(55.2%)	181(47.6%)
Female	12(54.5%)	85(65.3%)	102(44.7%)	199(52.3%)
Transgender	0(0%)	0(0%)	0(0%)	0(0%)
Marital status				
Single	17(77.2%)	92(70.7%)	108(47.3%)	217(57.1%)
Married	5(22.7%)	36(27.6%)	118(51.7%)	159(41.8%)
Divorced	0(0%)	1(0.7%)	2(0.8%)	3(0.7%)
Widow	0(0%)	1(0.7%)	0(0%)	1(0.2%)
Residence				
Urban	17(77.2%)	100(76.9%)	161(70.6%)	278(73.1%)

Rural	5(22.7%)	30(23%)	67(29.3%)	102(26.8%)
Family monthly income (Rs)				
<10000	0(0%)	9(6.9%)	25(10.9%)	34(8.9%)
10001- 20000	0(0%)	12(9.2%)	27(11.8%)	39(10.2%)
20001- 40000	6(27.2%)	30(23%)	59(25.8%)	95(25%)
40001- 60000	2(9%)	28(21.5%)	66(28.9%)	96(25.2%)
>60,000	14(63.6%)	51(39.2%)	51(22.3%)	116(30.5%)
Educational status				
Illiterate	1(4.5%)	1(0.7%)	4(1.7%)	6(1.5%)
Primary	4(18.1%)	3(2.3%)	16(7%)	23(6%)
10th	2(9%)	9(6.9%)	18(7.8%)	29(7.6%)
12th	5(22.7%)	42(32.3%)	85(37.2%)	132(34.7%)
Graduate & higher	10(45.4%)	75(57.6%)	105(46%)	190(50%)
Occupation				
Student	14(63.6%)	46(35.3%)	48(21%)	108(28.4%)
Unemployed	0(0%)	1(0.7%)	8(3.5%)	9(2.3%)
House maker	1(4.5%)	7(5.3%)	29(12.7%)	37(9.7%)
Govt. employee	0(0%)	5(3.8%)	13(5.7%)	18(4.7%)
Private job	7(31.8%)	68(52.3%)	90(39.4%)	165(43.45)
Business	0(0%)	3(53.8%)	40(17.5%)	43(11.3%)

Table 18. Comparison of attitude among different demographic variables

Variables	High attitude (N=159)	Moderate attitude (N=193)	Low attitude (N= 28)	Total (N=380)
Age in year				
18-28	101(63.5%)	111(57.5%)	19(67.8%)	231(60.7%)
29-39	38(23.8%)	63(32.6%)	6(21.4%)	107(28.1%)
40- 50	20(12.5%)	19(9.8%)	3(10.7%)	42(11%)
Gender				
Male	67(42.1%)	98(50.7%)	16(57.1%)	181(47.6%)
Female	92(57.8%)	95(49.2%)	12(42.8%)	199(52.3%)
Transgender	0(0%)	0(0%)	0(0%)	0(0%)
Marital status				
Single	88(55.3%)	111(57.5%)	18(64.2%)	217(57.1%)
Married	69(43.3%)	80(41.4)	10(35.7%)	159(41.8%)
Divorced	1(0.6%)	2(1%)	0(0%)	3(0.7%)
Widow	1(0.6%)	0(0%)	0(0%)	1(0.2%)
Residence				
Urban	116(72.9%)	140(72.5%)	22(78.5%)	278(73.1%)
Rural	43(27%)	53(27.4%)	6(21.4%)	102(26.8%)
Family monthly income (Rs)				
<10000	8(5%)	21(10.8%)	5(17.8%)	34(8.9%)
10001- 20000	17(10.6%)	16(8.2%)	6(21.4%)	39(10.2%)
20001- 40000	38(23.8%)	47(24.3%)	10(35.7%)	95(25%)
40001- 60000	46(28.9%)	49(25.3%)	1(3.5%)	96(25.2%)
>60,000	50(31.4%)	60(31%)	6(21.4%)	116(30.5%)
Educational status				
Illiterate	3(1.8%)	3(1.5%)	0(0%)	6(1.5%)
Primary	7(4.4%)	14(7.2%)	2(7.1%)	23(6%)
10th	16(10%)	13(6.7%)	0(0%)	29(7.6%)
12th	46(28.9%)	75(38.8%)	11(39.2%)	132(34.7%)
Graduate & higher	87(54.7%)	88(45.5%)	15(53.5%)	190(50%)

Occupation	52(32.7%)	52(26.9%)	4(14.2%)	108(28.4%)
Student	5(3.1%)	2(1%)	2(7.1%)	9(2.3%)
Unemployed	20(12.5%)	16(8.2%)	1(3.5%)	37(9.7%)
House maker	11(6.9%)	6(3.1%)	1(3.5%)	18(4.7%)
Govt. employee	55(34.5%)	92(47.6%)	18(64.2%)	165(43.4%)
Private job	16(10%)	25(12.9%)	2(7.1%)	43(11.3%)
Business				

5.16 Discussion

It was found that women used more cosmetics than men, presumably because women are more concerned with their physical attractiveness and beauty. Concordant to our results, two different studies from Tanzania (253) and India (230) reported high prevalence of cosmetics usage among women. Graham and Klingman stated in their book Psychology of Cosmetic that women appeared more positive after using cosmetics (254). The majority of users in our study were young (age group15-25 years). This may be because young people in this age range are more inclined to use cosmetics to improve their appearance (234). High rates of cosmetics use among the young have also been documented in other studies (233, 234). Graduates and those with advanced degrees were shown to be more willing to use cosmetics. This may be because people with higher levels of education, care more about their appearance, skin health, and beauty. In addition, those with higher levels of education are more likely to be exposed to multiple products via social media than those with lower levels of education. Personal care products (PCPs) were the most often utilized cosmetics in our survey. One explanation is that PCPs are regularly used by people of all ages to maintain hygienic conditions and odorlessness (255). A study from Saudi Arabia also reported high use of personal care products among the cosmetics users (233). In our study, the prevalence of adverse event was found to be 33%. A similar rate of adverse event was also reported in a study conducted in Nepal, with a rate of 31.2% (234). The reported rate of adverse events was highest in countries like Lithuania (80.4%), Saudi Arabia (50.6%), and Ethiopia (61%) (54, 229, 256). Possible explanations for this discrepancy include methodological and cultural differences between the study and the community being studied, as well as differences in the prevalence and nature

of cosmetic usage. A significant difference in the rate of occurrence of adverse event was found between males and females (AOR 1.77; 95% CI: 1.14–2.75). Females were found to be more susceptible to adverse events associated with cosmetics than males. This could be due to more and multiple cosmetics used by the females. In our study, the majority of adverse events were caused by skin care products followed by haircare and personal care products. Consistent with our findings, a study from Ethiopia reported that skin care and hair care cosmetics were the most common sources of adverse events (224, 228). This could be due to the widespread usage of these products. Itching, redness followed by pimples were the most commonly reported reactions experienced by cosmetic users. Consistent with our findings, Lucca et al. found that erythema of skin (19%), acne (15%), and itching (13%) were the most prevalent cosmetic-induced adverse events (233). Another study by Shaaban et al. reported that redness, itching & skin soreness were the commonly reported adverse events among cosmetics users (232). Lack of awareness on allergy test was found to be a predictor of adverse event in our study. Individuals with history of food or drug allergies were more likely to experience adverse events as against individuals with out history of allergy. This observation was in line with a significant proportion of participants not checking the constituents of the products in the present study. As cosmetics consist of a wide variety of chemicals, some of which they may be allergic to. Therefore, before using cosmetics, one should double-check the list of ingredients and preferably read the instructions as well. Similar result was also stated by Bilal et al., 2016 (54). Other predictors of adverse event included verifying the cosmetics' expiration date and frequently switching brands. Those checked expiry date of the products were more likely to be the one reported more adverse events as against the those did not check (AOR 1.9). This variance in the observation could likely be explained by the fact that individuals experiencing adverse events are likely to check the composition and expiry date more than those did not experience. However, a less likely significant association was seen between individuals who regularly switched brands of cosmetics and those who rarely did (AOR 0.50; 95% CI: 0.32–0.78). This could be due to the interactions between cosmetic items or synergistic effects of cosmetics (54, 221, 256).

The majority of AEs in our study were categorized as “not clearly attributable.” This could be due to individual variability in skin sensitivity, preexisting conditions, concurrent use of other products, and the community-based nature of the study. Similarly, a study by Al Mulla F. et al.(257) also found that most AEs were not clearly attributable. In contrast, a study by Jyrwa et al. (230) conducted in a tertiary care hospital found that most AEs were categorized as “likely.” This discrepancy may be due to differences in study settings and population characteristics.

The meta-analysis of cosmetic-induced adverse events has shown a concerning prevalence of 41.1%. The regional analysis showed varying prevalence rates of cosmetic-induced adverse events, with the highest rate observed in the African region at 53.6%, followed by comparatively lower rates in South America (38.0%), Asia (35.0%), and Europe (33.4%). These inconsistencies can be attributed to differences in cultural practices, regulatory frameworks, healthcare infrastructure, and socioeconomic factors. In the African region, the higher prevalence is related to lower literacy levels, limited emphasis on safety evaluations for non-medicated cosmetics (54, 258), and challenges in proper storage and handling due to the warm climate (54, 224). Similarly, an analysis based on participant types found a higher prevalence of cosmetic-induced adverse events among the student community at 51.1%, compared to 36.8% in the general population. This discrepancy may arise from students’ interest in beauty trends (228), leading to riskier cosmetic practices without strict adherence to safety guidelines (57). Students are more likely to experiment with various products, potentially increasing their exposure to substances that can trigger adverse reactions. Limited awareness and education on safe cosmetic use among students further contribute to the higher prevalence (259). Beyond the promises of beautiful skin and exciting colors, cosmetics can sometimes create problems for our skin (14). Certain ingredients, such as fragrance alcohols or harsh surfactants, have the potential to directly harm our skin, causing redness and dryness (46, 260). For some individuals, elements like nickel or formaldehyde in cosmetics can trigger the immune system, leading to itchy rashes or swelling (261). Exposure to sunlight can result in issues like burns or dark spots due to specific ingredients (262). Additionally, cosmetics containing substances like parabens or phthalates may disrupt hormonal balance,

potentially resulting in long-term health consequences (263, 264). The complexity does not always lie in isolated ingredients but in the unexpected interaction of multiple chemicals within a product, giving rise to unintended and undesirable reactions.

The prevalence of cosmetic-induced adverse events is influenced by various determinants, as found in our qualitative analysis. Habitual use of multiple cosmetics per day (53, 54) and frequent daily application (54) emerged as significant risk factors due to prolonged and repetitive exposure to diverse product formulations, increasing the likelihood of skin irritation or sensitization. The interaction between cosmetic products or their ingredients may contribute to these adverse events (54, 221, 265). Individuals with a personal or family history of allergies (50, 233) showed enhanced susceptibility, indicating that pre-existing allergic conditions may cause reactions to cosmetic ingredients. Additionally, a higher risk of adverse events was linked to both higher educational status (54) and urban residence (53), potentially arising from increased exposure among urban, educated populations to numerous cosmetic products (50). Conversely, individuals with lower educational status reported fewer adverse events (54), possibly influenced by cultural, religious, or social factors that result in reduced cosmetic usage (50, 54) . Moreover, good financial conditions were correlated with enhanced susceptibility (228), implying that increased financial resources might be related to the use of a broader range of cosmetic products due to the ability to afford more expensive items (228) . This, in turn, raises the risk of experiencing adverse events. Adverse events were also associated with the female gender (50) and younger age(54), likely due to higher cosmetic consumption driven by beauty concerns in these populations (50, 228). Reading product labels (53) and checking expiry dates (50) were important determinants influencing adverse event reporting, as those who encountered adverse events were more inclined to check product composition and expiration dates (50). Conversely, adverse events were associated with mixing different cosmetic products (54), combining them with saliva or water (54), frequent brand changes (50), and a lack of knowledge about allergy tests (50) . Combining cosmetic products with substances not specified by the manufacturer can alter the physical and chemical properties of the product, leading to

unintended chemical reactions and potential unexpected adverse events (54) . Furthermore, water and saliva, being conducive environments for bacterial growth, can also impact the concentrations of preservatives (57, 221).

Simplifying daily routines with fewer products can decrease the risk of adverse events (59). Additionally, testing cosmetics before applying them to detect potential adverse reactions, including allergies, is imperative (221). Targeted education campaigns, especially focusing on female populations, should encourage safe cosmetic practices. Emphasizing the selection of products based on skin type and sensitivity, along with promoting the practice of reading labels, including double-checking ingredient lists and expiry dates, is essential (50, 54). Raising awareness about the risks associated with mixing different products is also necessary. Addressing

the impact of adverse events on healthcare systems, individual health, and financial considerations is important for reducing healthcare costs and ensuring the safety of cosmetic product users. Collaborative efforts among healthcare professionals, regulatory bodies, and the industry are crucial to focus on patient safety and uphold public trust. This study supports the establishment of strong regulatory frameworks, including licensing requirements and a strict product approval process, to respond effectively to adverse events.

The rapid growth of the cosmetic industry in India, combined with the increasing accessibility and utilization of skincare products, emphasize the necessity of understanding the knowledge and attitudes of the Indian population towards cosmetics (266). Our investigation explored the knowledge and attitudes concerning cosmetic utilization and its associated adverse events, providing insightful perspectives into consumer behaviors and perceptions within the skincare and beauty product domain.

In this study, 22% of the participants had high knowledge on cosmetic utilization and adverse events, indicating a high level of poor knowledge among them. This finding aligns with studies in Saudi Arabia (267) and South Africa (268), where women exhibited limited awareness regarding cosmetics. However, it contrasts with studies among Korean (269) and Lebanese women (237), where the majority demonstrated a good awareness regarding cosmetics use. Approximately half of the participants did

not correctly identify the first step in facial skincare as cleanser milk, which is contrary to the findings in Lebanese women (237). However, the relatively lower recognition of oily skin as the appropriate type for using cosmetic powders suggests a potential area for improvement in consumer education, aligning with the findings of Chahine et al. (237). Additionally, while a substantial portion recognized vitamin C for its anti-aging properties, there remains scope for enhancing awareness, especially considering its prevalence in skincare products (270). The significant proportion aware of the optimal timing for sunscreen application is encouraging, indicating prior exposure to sun protection education, which aligns with findings from Chahine et al. (237) while contrasting with findings from a Malaysian study (271) and the study by Wang et al. (272). However, the relatively lower recognition of petroleum jelly as a primary lip balm ingredient highlights the need for increased emphasis on awareness of cosmetic ingredients among users. Similarly, the limited awareness of deep masks as a post-hair dyeing conditioner suggests gaps in understanding hair care routines. Moreover, the low awareness of the potential toxicity associated with heavy metals in cosmetics emphasizes the need for increased awareness of ingredient safety (273). A considerable number of participants recognized sunscreen for its role in reducing skin cancer risk, aligning with the findings from a study conducted by Wang et al. (272). However, the low awareness of fragrances in perfumes as a common cause of cosmetic-induced skin allergies and oil-based cosmetics as likely to have adverse effects on the skin advocates areas requiring targeted education efforts (274).

A significant number of participants in the study agreed that inappropriate use of cosmetic products could lead to adverse effects, emphasizing the importance of proper cosmetic use to avoid skin issues such as wrinkles, darkening, and rashes. Similar observations were reported in studies conducted in Lebanon (237) and India (275), indicating a growing awareness among consumers about the significance of skincare practices. Additionally, the majority of participants expressed a preference for quality over price in cosmetics, suggesting a general inclination toward prioritizing product effectiveness and safety over affordability. This attitude was also endorsed in a study conducted in Nepal (276), where consumers considered quality before price while purchasing cosmetics. Moreover, most participants asserted to trust cosmetics made

with organic herbal ingredients more than chemical-based ones, which is supported by results from studies conducted in the UK (277), Malaysia (278), and India (279). Similarly, there was a consensus among participants regarding the relationship between chemical hair dyes/bleaching and grey hair. Most participants had the belief that water could effectively be used for makeup removal, while opinions were divided on starting sunscreen use at a young age, highlighting the necessity for targeted education initiatives to promote proper makeup removal techniques and sunscreen practices. Furthermore, mixed responses regarding tattoos' potential to cause cancer suggested a lack of clarity among participants, emphasizing the importance of disseminating accurate information on tattoo safety.

In light of these findings, implementing targeted educational campaigns and collaborating with regulatory agencies and cosmetic manufacturers are imperative steps to enhance consumer safety and promote responsible cosmetic use. By developing a culture of critical thinking and consumer empowerment, stakeholders can mitigate the risk of adverse effects associated with cosmetic use, ultimately contributing to a safer and more reliable cosmetic industry.

Limitations

It is possible that this study has some limitation. First, information about cosmetic utilization pattern and adverse events was collected by a self-report questionnaire. So, there is a possibility of bias due to the fact that those who experienced an adverse event were more likely to participate in the survey and leads to underestimation. Second, adverse events reported by cosmetic users in this study was across a span of two years, hence findings of the study could be affected by recall bias. Third, duration of cosmetics uses and UV light exposure, history of medicine and medical problems were some confounders which was out of the scope of the study. Finally, as this is a cross sectional study so it gives a weak association between the exposure of cosmetics and related adverse events.

Systematic review and meta-analysis study has also some limitations that should be acknowledged. The reliance on self-recall data in primary studies introduces the potential for recall bias. Potential publication bias and study heterogeneity need to be

considered when interpreting results. Additionally, the assessment of determinants relied on data from a limited number of studies reporting adjusted odds ratios (AORs), which may affect interpretation.

CHAPTER - 6

6. Summary & Conclusion

Our objective was to investigate patterns of cosmetic usage, including associated adverse events, and to evaluate knowledge and attitudes towards cosmetics through community-based cross-sectional studies. Furthermore, we aimed to assess the prevalence of adverse events caused by cosmetics and elucidate associated factors through a systematic review and meta-analysis. Our cross-sectional study involving 400 participants revealed that a significant number of participants used cosmetics regularly, with makeup and personal care products being the most common. Additionally, many reported adverse events, emphasizing the need for increased awareness and education about using cosmetics wisely. This highlights the importance of establishing a cosmetovigilance center to monitor and address adverse events effectively. Furthermore, the systematic review and meta-analysis revealed highly prevalent adverse events associated with cosmetics globally, with a pooled prevalence of 41.1%. Regional differences were observed, with Africa showing the highest prevalence. Students were identified as a vulnerable group, requiring targeted interventions and enhanced vigilance. Key factors associated with adverse events included daily use of multiple cosmetics, urban residence, higher education, good financial status, female gender, and younger age. These findings stress the need for robust cosmetovigilance mechanisms, regulatory reforms, and enhanced consumer awareness worldwide.

Additionally, the assessment of knowledge and attitudes regarding cosmetic usage among 380 participants in Punjab, India, showed moderate levels of knowledge with important gaps, especially regarding the adverse effects of hair dyes and heavy metals in cosmetics. Attitudes inclined towards valuing quality over price, though concerns

about ingredient safety persisted. Younger individuals, females, and those with higher education demonstrated higher levels of knowledge and positive attitudes. This highlights the importance of targeted educational interventions to promote safer cosmetic practices and effectively mitigate adverse events.

The prevalence of adverse events among cosmetics users was identified to be considerable, highlighting a concerning trend. Concurrently, our research revealed a

notable deficiency in adequate knowledge regarding cosmetics and their associated adverse events among users. This emphasizes the crucial necessity to cultivate awareness regarding the judicious use of cosmetics within the community. In light of these findings, there is a clear imperative for the implementation of cosmetovigilance measures, regulatory enhancements, and heightened consumer awareness initiatives. Cosmetovigilance mechanisms can facilitate the systematic monitoring and reporting of adverse events related to cosmetic usage, enabling timely intervention and risk mitigation strategies. Regulatory enhancements are essential to strengthen oversight mechanisms, ensuring the safety and efficacy of cosmetics available in the market. Moreover, initiatives aimed at enhancing consumer awareness play a pivotal role in empowering individuals to make informed choices regarding cosmetic products. Educating consumers about potential risks associated with certain ingredients or improper usage practices can contribute significantly to minimizing adverse events and promoting safer cosmetic practices.

CHAPTER - 7

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Annexures

IEC approval letter

Annexure: I

LOVELY PROFESSIONAL UNIVERSITY
Transforming Education Transforming India

Lovely School of Pharmaceutical Sciences

INSTITUTIONAL ETHICS COMMITTEE
Lovely Professional University, Punjab
Ph: +91-1824-444039; E-mail: ao_pharma.lit@lpu.co.in

Chairperson:
Dr. H. S. Gill

Deputy Chairman:
Dr. Monica Gulati

Members:
Dr. Shivani Tandon
Dr. Naresh Kundra
Dr. N. K. Gupta
Dr. Meenu Chopra
Mr. Dharminder Singh Dhillon
Dr. Sasmita Kaur
Sardar Nagina Singh

Member Secretary:
Dr. Navneet Khurana

Ref. No: LPU/IEC/2021/01/33

Date: 17.03.21

To

Sweta Kumari,

School of Pharmaceutical science,

Lovely Professional University (Punjab)

Dear Sir/Madam,

The Ethics committee has studied the research proposal submitted by Sweta Kumari on research topic **"Assessment of cosmetic utilization pattern and adverse effects associated with it".**

It has been decided to accord **approval** to this study protocol.

Thanking You.

Your sincerely

(Member Secretary)

Jalandhar-Delhi G.T.Road, Phagwara, Punjab (India) - 144411
Ph : +91-1824-444039 Fax : +91-1824-240430 E-mail : info@lpu.co.in website : www.lpu.in

Annexure I

LOVELY PROFESSIONAL UNIVERSITY
Transforming Education Transforming India

INSTITUTIONAL ETHICS COMMITTEE (IEC)
(Registration No: EC/NEW/INST/2022/3110)

Ref: LPU/IEC-LPU/2023/1/25
Date: 15.10.23

Dear Sweta Kumari

The Institutional Ethics Committee, Lovely Professional University (IEC-LPU) reviewed and discussed your application to conduct the study entitled **"To assess the knowledge and attitude regarding cosmetic utilization and associated adverse events."**

The following documents were reviewed:
(a) Application form
(b) Research Protocol
(b) Patient information sheet and informed consent form in English or vernacular language.
(c) Principal investigator's current Curriculum Vitae.

The following members of the ethics committee were present at the meeting held on 28.09.23

Sr. No	Name	Designation as per IEC
1	Dr. Shivani Tandon	Chairperson
2	Dr. Navneet Khuruna	Member Secretary
3	Dr. Kanav Khera	Alternate Member Secretary
4	Dr. Varun Gupta	Basic Medical Scientist
5	Dr. Naresh Kundra	Clinician-I
7	Dr. Meenu Chopra	Legal expert
8	Mr. Sumesh Mathew	Social scientist/Philosopher/Ethicist/Theologian
9	Dr. Rajan Kumar Sharma	Layperson

The Ethics committee **approved** the study to be conducted in its presented form subject to the condition of

- The principal investigator and all members of the project shall ensure compliance with current regulatory provisions (as per New Drug Clinical Trial Rules 2019 and ICH-GCP), Ethical Guidelines for Biomedical Research on Human Participants by ICMR, and the standard operating procedure of IEC including timely submission of Interim Annual Report and Final Closure Report.
- Participant Information Sheet and a copy of signed Informed Consent shall be given to every research participant.
- Inform IEC in case of any proposed amendments (change in protocol/procedure, site / Investigator, etc).
- Inform IEC immediately in case of any Adverse Events and Serious Adverse Events.
- Members of the IEC have the right to monitor any project with prior intimation.

Yours sincerely,

15.10.23
Chairperson/Member secretary/Alternate member secretary, IEC-LPU **dd/mm/yyyy**

Member Secretary
Institutional Ethics Committee
Lovely Professional University
Phagwara-Punjab-144411

NAAC GRADE A++

Jalandhar-Delhi G.T. Road, Phagwara, Punjab (India) - 144411
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Questionnaire

Annexure II

Name ……
Date ……...
Place …….

Evaluation of the cosmetic utilization pattern and associated adverse events

SECTION A : SOCIODEMOGRAPHIC CHARACTERISTICS

S/No.		S/No.	
1	**Age (year):**	2	**Gender:** a) Male ……. b) Female …… c) Transgender…….
3	**Marital status** a) Single b) Married c) Divorced d) Widow	4	**Personal history of allergic to any medicines or foods** a) Yes b) No **Family history of allergy** a) Yes b) No
5	**Residence** a) Urban b) Rural	6	**Monthly income (Rs)** a) <10000 b) 10001- 20000 c) 20001- 40000 d) 40001- 60000 e) >60,000

7	**Educational status** a) Illiterate b) Primary c) 10^{th} d) 12^{th} e) Graduate & Higher	8	**Occupation** a) Student b) Unemployed c) House maker d) Govt. Employee e) Private Job f) Business

Signature of

Participant

SECTION B: COMESTIC USAGE PATTERN

S/No.		S/No.	
1	**Number of cosmetics used per day** a) 1-2 b) 3-5 c) 6-8 d) >8	2	**Type of cosmetics used** a) Hair Care Hair gel ☐ Hair dye ☐ Hair wax ☐ Hair spray ☐ Shampoo ☐ Conditioner ☐ Hair oil ☐ Permanent waves/straight ☐ Any others ☐ b) Skin care Lotion ☐ Cream ☐ Toner ☐ Face mask ☐ Moisturizer ☐ Scrub ☐ Any others ☐ c) Make up Eye liner ☐ Mascaras ☐ Lipstick ☐ Foundation ☐Powder ☐ Eye shadow ☐ Concealer ☐ Blush palette ☐Kajal ☐ Eyebrow pencil ☐ Any others ☐ d) Nail Care Nail polish ☐ Nail polish remover ☐ Any others ☐ e) Personal care Soap ☐ Face wash ☐Deodorant ☐ Toothpaste ☐Shaving cream☐ Foam ☐ Hair remover cream☐ Wax ☐ Any others ☐ f) Traditional cosmetic Mud mask ☐ Henna ☐ Others ☐

			g) Perfume ☐
3	**Read the instruction in label** a) Yes b) No c) Sometimes	4	**Testing of allergy** a) Yes b) No c) Do Not Know
5	**Change cosmetic brand** a) Yes b) No	6	**Sharing cosmetics with friends/family** a) Yes b) No
7	**Purpose of use** a) Cleansing b) Beautification c) Protection d) Medication e) Whitening f) Anti-aging g) Hair coloring	8	**Source of cosmetics** a) Drug store b) Shopping mall c) Local shop d) Cosmetic store e) Online f) Mixed
9	**Adding water/other agent in cosmetic** a) Yes b) No	10	**Number of times cosmetics used per day** a) 1 b) 2 c) 3 d) > 3
11	**Check expiry date** a) Yes b) No	12	**Proper storage as indicated on the label of the product** a) Yes b) No

SECTION C: ADVERSE REACTION

S/No.		S/No.	
1	**Did you experience any side effectsin last 2 years?** a) Yes b) No c) Do Not Know If **No** kindly skip remaining question	2	**What side effects did you experience?** a) Itching b) Redness c) Darkening d) Burning sensation e) Edema f) Pain g) Eye irritation h) Pimples i) Hair loss j) Pigmentation k) Headache l) Any others…

3	**Location of side effects**	4	**How were the side effects managed?** a) Stop using the products b) Consulted physician c) Medication used d) Any other
5	**Which type of cosmetic caused this side effect?**		

Signature of Participant

Annexure II

नाम ……

दिनांक ……...
स्थान ……..……

कॉस्मेटिक उपयोग पैटर्न और संबंधित प्रतिकूल घटनाओं का मूल्यांकन

खंड क: सामाजिक-जनसांख्यिकीय विशेषताएं

S/No.		S/No.	
1	**आयु (वर्ष):**	2	**लिंग:** क) पुरुष …… ख) महिला …… ग) ट्रांसजेंडर …….
3	**वैवाहिक स्थिति** क) अविवाहित ख) विवाहित ग) तलाकशुदा घ) विधवा	4	**किसी भी दवा या खाद्य पदार्थ से एलर्जी का व्यक्तिगत इतिहास** क) हाँ ख) नहीं **एलर्जी का पारिवारिक इतिहास** क) हाँ ख) नहीं
5	**निवास स्थान** क) शहरी ख) ग्रामीण	6	**मासिक आय (रु.)** क) <10000 ख) 10001- 20000 ग) 20001- 40000 घ) 40001- 60000 ङ)> 60,000
7	**शैक्षिक स्थिति** क) निरक्षर ख) प्राथमिक ग) 10 वीं घ) 12वीं ङ) स्नातक और उच्चतम	8	**व्यवसाय** क) विद्यार्थी ख) बेरोजगार ग) गृहिणी घ) सरकारी कर्मचारी ङ) निजी नौकरी

			च) व्यापार

खंड ख: सौंदर्य प्रसाधनों का उपयोग

S/No.		S/No.	
1	**प्रतिदिन उपयोग किए जाने वाले सौंदर्य प्रसाधनों की संख्या** क) 1-2 ख) 3-5 ग) 6-8 घ) >8	2	**उपयोग किए गए सौंदर्य प्रसाधनों के प्रकार** **क) बालों की देखभाल** हेयर जेल ☐हेयर डाई ☐हेयर वैक्स ☐ हेयर स्प्रे ☐ शैम्पू कंडीशनर ☐ बालों का तेल ☐ स्थायी तरंगें / सीधी☐ अन्य ☐ **ख) त्वचा की देखभाल** लोशन☐ क्रीम ☐टोनर ☐फेस मास्क☐ मॉइस्चराइजर ☐ स्क्रब ☐ अन्य ☐ **ग) मेकअप** आई लाइनर☐ मस्कारा ☐लिपस्टिक ☐ फाउंडेशन पाउडर ☐ आई शैडो ☐ कंसीलर ☐ ब्लश पैलेट ☐ काजल ☐ आइब्रो पेंसिल ☐ अन्य ☐ **घ) नाखून की देखभाल** नेल पॉलिश ☐ नेल पॉलिश रिमूवर ☐ अन्य ☐ **ङ) व्यक्तिगत देखभाल** साबुन ☐ फेस वाश ☐डिओडोरेंट ☐ टूथपेस्ट ☐ शेविंग क्रीम ☐फोम☐ हेयर रिमूवर क्रीम ☐ वैक्स ☐ अन्य ☐ **च) पारंपरिक कॉस्मेटिक** मिट्टी का मुखौटा ☐ मेंहदी ☐ अन्य ☐ **छ)** इत्र ☐
3	**लेबल में निर्देश पढ़ें** क) हाँ ख) नहीं ग) कभी-कभी	4	**एलर्जी का परीक्षण** क) हाँ ख) नहीं ग) नहीं पता
5	**कॉस्मेटिक ब्रांड बदलें** क) हाँ ख) नहीं	6	**मित्रों/परिवार के साथ सौंदर्य प्रसाधन साझा करना** क) हाँ ख) नहीं

7	**उपयोग करने का उद्देश्य** क) सफाई ख) सौंदर्यीकरण ग) संरक्षण घ) दवा ङ) सफेदी च) एंटी-एजिंग छ) बालों को रंगना	8	**सौंदर्य प्रसाधनों का स्रोत** क) ड्रगस्टोर ख) शॉपिंग मॉल ग) स्थानीय दुकान घ) कॉस्मेटिक स्टोर ङ) ऑनलाइन च) मिश्रित
9	**कॉस्मेटिक में पानी / अन्य एजेंट जोड़ना** क) हाँ ख) नहीं	10	**एक दिन में कितने बार सौंदर्य प्रसाधनों का उपयोग किया जाता है** क) 1 ख) 2 ग) 3 घ) > 3
11	**एक्सपायरी डेट चेक करें** क) हाँ ख) नहीं	12	**उत्पाद के लेबल पर बताए अनुसार उचित भंडारण** क) हाँ ख) नहीं

खंड ग: प्रतिकूल प्रतिक्रिया

S/No.		S/No.	
1	**क्या आपने पिछले** दो **वर्षों में कोई दुष्प्रभाव अनुभव किया है?** क) हाँ ख) नहीं ग) नहीं पता यदि नहीं, तो कृपया शेष प्रश्न 2 को छोड़ दें	2	**पने किन दुष्प्रभावों का अनुभव किया?** क) खुजली ख) लाली ग) काला पड़ना घ) जलन की अनुभूति ङ) सूजन च) दर्द छ) आंखों में जलन ज) मुंहासे झ) बालों का झड़ना ञ) रंजकता ट) सिरदर्द ठ) कोई अन्य ...
3	**साइड इफेक्ट का स्थान**	4	**साइड इफेक्ट का प्रबंधन कैसे किया गया?** क) उत्पादों का उपयोग करना बंद किया ख) चिकित्सक परामर्श ग) दवा का उपयोग

			घ) कोई अन्य
5	**किस प्रकार के कॉस्मेटिक के कारण यह दुष्प्रभाव हुआ?**		

Annexure II

ਨਾਮ .....

ਤਾਰੀਖ਼ .....
ਸਥਾਨ.....

ਕਾਸਮੈਟਿਕ ਉਪਯੋਗਤਾ ਪੈਟਰਨ ਅਤੇ ਸੰਬੰਧਿਤ ਪ੍ਰਤੀਕੂਲ ਘਟਨਾਵਾਂ ਦਾ ਮੁਲਾਂਕਣ
ਸੈਕਸ਼ਨ ਏ: ਸਮਾਜ-ਵਿਗਿਆਨਕ ਵਿਸ਼ੇਸ਼ਤਾਵਾਂ

1	**ਉਮਰ (ਸਾਲ):**	2	**ਲਿੰਗ:** a) ਮਰਦ …… b) ਔਰਤ …… c) ਟ੍ਰਾਂਸਜੈਂਡਰ……..
3	**ਵਿਵਾਹਿਕ ਦਰਜਾ** a) ਸਿੰਗਲ b) ਵਿਆਹਿਆ ਹੋਇਆ c) ਤਲਾਕਸ਼ੁਦਾ d) ਵਿਧਵਾ	4	**ਕਿਸੇ ਵੀ ਦਵਾਈਆਂ ਜਾਂ ਭੋਜਨ ਤੋਂ ਐਲਰਜੀ ਦਾ ਨਿੱਜੀ ਇਤਿਹਾਸ** a) ਹਾਂ b) ਨਹੀਂ **ਐਲਰਜੀ ਦਾ ਪਰਿਵਾਰਕ ਇਤਿਹਾਸ** a) ਹਾਂ b) ਨਹੀਂ
5	ਨਿਵਾਸ a) ਸ਼ਹਿਰੀ b) ਪੇਂਡੂ	6	ਮਹੀਨਾਵਾਰ ਆਮਦਨ (ਰੁਪਏ) a) <10000 b) 10001-20000 c) 20001- 40000 d) 40001- 60000 e) >60,000
7	ਵਿਦਿਅਕ ਸਥਿਤੀ a) ਅਨਪੜ੍ਹ b) ਪ੍ਰਾਇਮਰੀ c) 10ਵੀਂ d) 12ਵੀਂ e) ਗ੍ਰੈਜੂਏਟ ਜਾਂ ਵੱਧ	8	ਕਿੱਤਾ a) ਵਿਦਿਆਰਥੀ b) ਬੇਰੁਜ਼ਗਾਰ c) ਘਰ ਬਣਾਉਣ ਵਾਲਾ d) ਸਰਕਾਰ ਕਰਮਚਾਰੀ e) ਨਿਜੀ ਨੌਕਰੀ f) ਵਪਾਰ

ਭਾਗੀਦਾਰਾਂ ਦੇ ਦਸਤਖਤ

ਸੈਕਸ਼ਨ B: ਕਾਸਮੈਟਿਕ ਵਰਤੋਂ ਪੈਟਰਨ

S/No.		S/No.	
1	ਪ੍ਰਤੀ ਦਿਨ ਵਰਤੇ ਜਾਣ ਵਾਲੇ ਕਾਸਮੈਟਿਕਸ ਦੀ ਸੰਖਿਆ a) 1-2 b) 3-5 c) 6-8 d) > 8	2	ਵਰਤੇ ਗਏ ਕਾਸਮੈਟਿਕਸ ਦੀ ਕਿਸਮ a) ਵਾਲਾਂ ਦੀ ਦੇਖਭਾਲ ਹੇਅਰ ਜੈੱਲ ☐ ਹੇਅਰ ਡਾਈ ☐ ਵਾਲ ਮੋਮ ☐ ਹੇਅਰ ਸਪਰੇਅ ☐ ਸ਼ੈਂਪੂ ☐ਕੰਡੀਸ਼ਨਰ ਵਾਲਾਂ ਦਾ ਤੇਲ ☐ਸਥਾਈ ਲਹਿਰਾਂ/ਸਿੱਧਾ ☐ ਕੋਈ ਹੋਰ ☐ b) ਚਮੜੀ ਦੀ ਦੇਖਭਾਲ ਲੋਸ਼ਨ ☐ ਕਰੀਮ ☐ ਟੋਨਰ ☐ ਫੇਸ ਮਾਸਕ ☐ ਮੋਇਸਚਰਾਈਜ਼ਰ ☐ ਸਕ੍ਰੱਬ ☐ ਕੋਈ ਹੋਰ ☐ c) ਮੇਕਅੱਪ ਆਈ ਲਾਈਨਰ ☐ ਮਸਕਰਾਸ ☐ ਲਿਪਸਟਿਕ ☐ ਫਾਊਂਡੇਸ਼ਨ ☐ ਪਾਊਡਰ ☐ ਆਈ ਸ਼ੈਡੋ ☐ ਕੰਸੀਲਰ ☐ ਬਲੱਸ਼ ਪੈਲੇਟ ☐ ਕਾਜਲ ☐ ਆਈਬ੍ਰੋ ਪੈਨਸਿਲ ☐ ਕੋਈ ਹੋਰ ☐ d) ਨਹੁੰ ਦੀ ਦੇਖਭਾਲ ਨੇਲ ਪਾਲਿਸ਼ ☐ ਨੇਲ ਪਾਲਿਸ਼ ਰਿਮੂਵਰ ☐ ਕੋਈ ਹੋਰ ☐ e) ਨਿੱਜੀ ਦੇਖਭਾਲ ਸਾਬਣ ☐ ਫੇਸ ਵਾਸ਼ ☐ ਡੀਓਡੋਰੈਂਟ ☐ ਟੂਥਪੇਸਟ ☐ ਸ਼ੇਵਿੰਗ ਕਰੀਮ ☐ ਫੋਮ ☐ ਹੇਅਰ ਰਿਮੂਵਰ ਕ੍ਰੀਮ☐ ਵੈਕਸ ☐ ਕੋਈ ਹੋਰ ☐ f) ਪਰੰਪਰਾਗਤ ਕਾਸਮੈਟਿਕ ਮਡ ਮਾਸਕ ☐ ਹੈਨਾ ☐ ਹੋਰ ☐ g) ਅਤਰ ☐
3	ਲੇਬਲ ਵਿੱਚ ਨਿਰਦੇਸ਼ ਪੜ੍ਹੋ a) ਹਾਂ b) ਨਹੀਂ c) ਕਈ ਵਾਰ	4	ਐਲਰਜੀ ਦੀ ਜਾਂਚ a) ਹਾਂ b) ਨਹੀਂ c) ਨਹੀ ਜਾਣਦਾ

5	ਕਾਸਮੈਟਿਕ ਬ੍ਰਾਂਡ ਬਦਲੋ a) ਹਾਂ b) ਨਹੀਂ	6	ਦੋਸਤਾਂ/ਪਰਿਵਾਰ ਨਾਲ ਸ਼ਿੰਗਾਰ ਸਮੱਗਰੀ ਸਾਂਝੀ ਕਰਨਾ a) ਹਾਂ b) ਨਹੀਂ
7	**ਵਰਤੋਂ ਦਾ ਉਦੇਸ਼** a) ਸਫਾਈ b) ਸੁੰਦਰਤਾ c) ਸੁਰੱਖਿਆ d) ਦਵਾਈ e) ਚਿੱਟਾ ਕਰਨਾ f) ਬੁਢਾਪਾ ਵਿਰੋਧੀ g) ਵਾਲਾਂ ਦਾ ਰੰਗ	8	**ਸ਼ਿੰਗਾਰ ਦਾ ਸਰੋਤ** a) ਡਰੱਗ ਸਟੋਰ b) ਸ਼ਾਪਿੰਗ ਮਾਲ c) ਸਥਾਨਕ ਦੁਕਾਨ d) ਕਾਸਮੈਟਿਕ ਸਟੋਰ e) ਔਨਲਾਈਨ f) ਮਿਸ਼ਰਤ
9	**ਕਾਸਮੈਟਿਕ ਵਿੱਚ ਪਾਣੀ/ਹੋਰ ਏਜੰਟ ਸ਼ਾਮਲ ਕਰਨਾ** a) ਹਾਂ b) ਨਹੀਂ	10	ਪ੍ਰਤੀ ਦਿਨ ਵਰਤੇ ਜਾਣ ਵਾਲੇ ਕਾਸਮੈਟਿਕਸ ਦੀ ਗਿਣਤੀ a) 1 b) 2 c) 3 d) > 3
11	**ਮਿਆਦ ਪੁੱਗਣ ਦੀ ਮਿਤੀ ਦੀ ਜਾਂਚ ਕਰੋ** a) ਹਾਂ b) ਨਹੀਂ	12	**ਉਤਪਾਦ ਦੇ ਲੇਬਲ 'ਤੇ ਦਰਸਾਏ ਅਨੁਸਾਰ ਸਹੀ ਸਟੋਰੇਜ** a) ਹਾਂ b) ਨਹੀਂ

ਭਾਗੀਦਾਰਾਂ ਦੇ ਦਸਤਖਤ

ਸੈਕਸ਼ਨ C: ਉਲਟ ਪ੍ਰਤੀਕਰਮ

ਸੈਕਸ਼ਨ C: ਉਲਟ ਪ੍ਰਤੀਕਰਮ

S/No.		S/No.	
1	ਕੀ ਤੁਸੀਂ ਪਿਛਲੇ 2 ਸਾਲਾਂ ਵਿੱਚ ਕਿਸੇ ਮਾੜੇ ਪ੍ਰਭਾਵਾਂ ਦਾ ਅਨੁਭਵ ਕੀਤਾ ਹੈ? a) ਹਾਂ b) ਨਹੀਂ c) ਪਤਾ ਨਹੀਂ ਜੇਕਰ ਨਹੀਂ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਬਾਕੀ ਸਵਾਲ ਛੱਡ ਦਿਓ	2	ਤੁਸੀਂ ਕਿਹੜੇ ਮਾੜੇ ਪ੍ਰਭਾਵਾਂ ਦਾ ਅਨੁਭਵ ਕੀਤਾ ਹੈ? a) ਖੁਜਲੀ b) ਲਾਲੀ c) ਹਨੇਰਾ ਕਰਨਾ d) ਜਲਣ ਦੀ ਭਾਵਨਾ e) ਐਡੀਮਾ f) ਦਰਦ g) ਅੱਖਾਂ ਦੀ ਜਲਣ h) ਮੁਹਾਸੇ i) ਵਾਲ ਝੜਨਾ j) ਪਿਗਮੈਂਟੇਸ਼ਨ k) ਸਿਰ ਦਰਦ l) ਕੋਈ ਹੋਰ...
3	**ਮਾੜੇ ਪ੍ਰਭਾਵਾਂ ਦਾ ਸਥਾਨ**	4	ਮਾੜੇ ਪ੍ਰਭਾਵਾਂ ਦਾ ਪ੍ਰਬੰਧਨ ਕਿਵੇਂ ਕੀਤਾ ਗਿਆ ਸੀ? a) ਉਤਪਾਦਾਂ ਦੀ ਵਰਤੋਂ ਬੰਦ ਕਰੋ b) ਡਾਕਟਰ ਦੀ ਸਲਾਹ ਲਈ c) ਵਰਤੀ ਗਈ ਦਵਾਈ d) ਕੋਈ ਹੋਰ
5	**ਕਿਸ ਕਿਸਮ ਦੇ ਕਾਸਮੈਟਿਕ ਨੇ ਇਹ ਮਾੜਾ ਪ੍ਰਭਾਵ ਪੈਦਾ ਕੀਤਾ?**		

Annexure III

To assess the knowledge and attitude regarding cosmetic utilization & associated adverse events

Serial no.------

Place ----------

Section A: Sociodemographic characteristics

S/No.	
1	Age (year):
2	Gender: a) Male b) Female c) Transgender
3	Marital status: a) Single b) Married c) Divorced d) Widow
4	Residence: a) Urban b) Rural
5	Family Monthly income (Rs): a) <10000 b) 10001- 20000 c) 20001- 40000 d) 40001- 60000 e) >60,000
6	Educational status: a) Illiterate b) Primary c) 10^{th} d) 12^{th} e) Graduate & Higher
7	Occupation: a) Student b) Unemployed c) House maker d) Govt. Employee e) Private Job f) Business

Section B: Knowledge regarding cosmetics utilization and adverse events

S/No	
1	What is the first step in facial skincare? a) Moisturizer b) Cleanser Milk c) Toner d) Don't Know
2	Which is the appropriate skin type for using cosmetic powders? a) Oily skin b) Sensitive skin c) Dry skin d) Don't know
3	Which vitamin is commonly found in skincare products and is known for antiaging properties? a) Vitamin A b) Vitamin B c) Vitamin C d) Don't know
4	When should sunscreen be applied before sun exposure? a) 15-30 minutes before sun exposure b) 1-2 hours before sun exposure c) It doesn't matter when you apply sunscreen d) Don't know
5	What is the main ingredients in most lip balm that help moisturize the lip? a) Bee wax b) Petroleum jelly c) Coconut oil d) Don't know
6	What is an appropriate conditioner to use after hair dyeing? a) Regular hair conditioner b) Deep mask c) Hair gel d) Don't know
7	What is the most common side effect of hair dyes? a) Dandruff b) Increased oiliness c) Wrinkles d) Don't know
8	Which metal, when present in elevated levels in cosmetics can lead to toxicities with prolonged use a) Heavy metal b) Zinc c) Copper d) Don't know
9	Which cosmetics help in reducing the risk of skin cancer? a) Lipstick b) Foundation c) Sunscreen d) Don't Know
10	What is the most common cause of cosmetic-induced skin allergy? a) Fragrances in perfumes b) Artificial dyes in makeup c) Emollients in moisturizers d) Don't Know
11	Which type of cosmetics is most likely to have side effects on the skin? a) Water-based cosmetics b) Oil-free cosmetics c) Oil based cosmetics d) Don't know

Section C: Attitude regarding cosmetics utilization and adverse events

S/No.	
1	Use of cosmetics inappropriately can lead to wrinkles, skin darkening, and rashes. 1.Strongly Disagree 2. Disagree 3.No idea 4.Agree 5.Strongly Agree
2	Quality matters more than price in cosmetics. 1.Strongly Disagree 2. Disagree 3.No idea 4.Agree 5.Strongly Agree
3	Are cosmetics made with organic herbal ingredients safer and healthier? 1.Strongly Disagree 2. Disagree 3.No idea 4.Agree 5.Strongly Agree
4	Can a tattoo cause cancer? 1.Strongly Disagree 2. Disagree 3.No idea 4.Agree 5.Strongly Agree
5	Grey hair could be a side effect of chemical hair dyes and bleaching. 1.Strongly Disagree 2. Disagree 3.No idea 4.Agree 5.Strongly Agree
6	It is important to start using sunscreen at a young age. 1.Strongly Disagree 2. Disagree 3.No idea 4.Agree 5.Strongly Agree
7	Usually, water is used to remove makeup. 1.Strongly Disagree 2. Disagree 3.No idea 4.Agree 5.Strongly Agree

Annexure III

क्रमांक----------

स्थान .....

खंड क: सामाजिक-जनसांख्यिकीय विशेषताएं

S.No	
1	**आयु (वर्ष):**
2	**लिंग:** क) पुरुष ख) महिला ग) ट्रांसजेंडर
3	**वैवाहिक स्थिति** क) अविवाहित ख) विवाहित ग) तलाकशुदा घ) विधवा
4	**निवास स्थान** क) शहरी ख) ग्रामीण
5	**मासिक आय (रु.)** क) <10000 ख) 10001- 20000 ग) 20001- 40000 घ) 40001- 60000 ङ)> 60,000
6	**शैक्षिक स्थिति** क) निरक्षर ख) प्राथमिक ग) 10 वीं घ) 12वीं ङ) स्नातक और उच्चतम
7	**व्यवसाय** क) विद्यार्थी ख) बेरोजगार ग) गृहिणी घ) सरकारी कर्मचारी ङ) निजी नौकरी च) व्यापार

खंड ख: सौंदर्य प्रसाधनों के उपयोग और प्रतिकूल घटनाओं के संबंध में ज्ञान

S.No	
1	चेहरे की त्वचा की देखभाल में पहला कदम क्या है? क) मॉइस्चराइजर ख) क्लींजर मिल्क ग) टोनर घ) पता नहीं
2	कॉस्मेटिक पाउडर का उपयोग करने के लिए उपयुक्त त्वचा का प्रकार कौन सा है? क) तैलीय त्वचा ख) संवेदनशील त्वचा ग) शुष्क त्वचा घ) पता नहीं
3	कौन सा विटामिन आमतौर पर त्वचा देखभाल उत्पादों में पाया जाता है और बुढ़ापा रोधी गुण के लिए जाना जाता है? क) विटामिन ए ख) विटामिन बी ग) विटामिन सी घ) पता नहीं
4	धूप में निकलने से पहले सनस्क्रीन कब लगाना चाहिए? क) धूप में निकलने से 15-30 मिनट पहले ख) धूप में निकलने से 1-2 घंटे पहले ग) इससे कोई फर्क नहीं पड़ता कि आप सनस्क्रीन कब लगाते हैं। घ) पता नहीं
5	अधिकांश लिप बाम में मुख्य तत्व क्या होते हैं जो होंठों को मॉइस्चराइज़ करने में मदद करते हैं? क) मधुमक्खी मोम ख) पेट्रोलियम जेली ग) नारियल तेल घ) पता नहीं
6	बालों को रंगने के बाद उपयोग के लिए उपयुक्त कंडीशनर कौन सा है? क) नियमित हेयर कंडीशनर ख) डीप मास्क ग) हेयर जेल घ) पता नहीं
7	हेयर डाई का सबसे आम दुष्प्रभाव क्या है? क) रूसी ख) तैलीयपन बढ़ना ग) झुर्रियाँ घ) पता नहीं
8	लंबे समय तक उपयोग के साथ, सौंदर्य प्रसाधनों में उच्च स्तर पर मौजूद होने पर कौन सी धातु विषाक्तता का कारण बन सकती है? क) भारी धातु ख) जिंक ग) तांबा घ) पता नहीं
9	कौन से सौंदर्य प्रसाधन त्वचा कैंसर के खतरे को कम करने में मदद करते हैं? क) लिपस्टिक ख) फाउंडेशन ग) सनस्क्रीन घ) पता नहीं
10	कॉस्मेटिक-प्रेरित त्वचा एलर्जी का सबसे आम कारण क्या है? क) इत्र में सुगंध ख) मेकअप में कृत्रिम रंग ग) मॉइस्चराइज़र में इमोलिएंट घ) पता नहीं
11	किस प्रकार के सौंदर्य प्रसाधनों का त्वचा पर दुष्प्रभाव सबसे अधिक होता है? क) पानी आधारित सौंदर्य प्रसाधन ख) तेल मुक्त सौंदर्य प्रसाधन ग) तेल आधारित सौंदर्य प्रसाधन घ) पता नहीं

खंड ग: सौंदर्य प्रसाधनों के उपयोग और प्रतिकूल घटनाओं के संबंध में दृष्टिकोण

S.No	
1	अनुचित तरीके से सौंदर्य प्रसाधनों के उपयोग से झुर्रियाँ, त्वचा का काला पड़ना और चकत्ते हो सकते हैं। क) पूरी तरह से असहमत ख) असहमत ग) कोई विचार नहीं सहमत घ) पूरी तरह से सहमत
2	सौंदर्य प्रसाधनों में कीमत से अधिक गुणवत्ता मायने रखती है। क) पूरी तरह से असहमत ख) असहमत ग) कोई विचार नहीं सहमत घ) पूरी तरह से सहमत
3	क्या जैविक हर्बल सामग्री से बने सौंदर्य प्रसाधन सुरक्षित और स्वास्थ्यवर्धक हैं? क) पूरी तरह से असहमत ख) असहमत ग) कोई विचार नहीं सहमत घ) पूरी तरह से सहमत
4	क्या टैटू से कैंसर हो सकता है? क) पूरी तरह से असहमत ख) असहमत ग) कोई विचार नहीं सहमत घ) पूरी तरह से सहमत
5	सफ़ेद बाल रासायनिक हेयर डाई और ब्लीचिंग का दुष्प्रभाव हो सकता है। क) पूरी तरह से असहमत ख) असहमत ग) कोई विचार नहीं सहमत घ) पूरी तरह से सहमत
6	कम उम्र में सनस्क्रीन का उपयोग शुरू करना महत्वपूर्ण है। क) पूरी तरह से असहमत ख) असहमत ग) कोई विचार नहीं सहमत घ) पूरी तरह से सहमत
7	आमतौर पर मेकअप हटाने के लिए पानी का इस्तेमाल किया जाता है। क) पूरी तरह से असहमत ख) असहमत ग) कोई विचार नहीं सहमत घ) पूरी तरह से सहमत

Annexure III

ਸੀਰੀਅਲ ਨੰਬਰ ------

ਸਥਾਨ ----------

ਸੈਕਸ਼ਨ ਏ: ਸਮਾਜ-ਵਿਗਿਆਨਕ ਵਿਸ਼ੇਸ਼ਤਾਵਾਂ

ਕ੍ਰਮ ਸੰਖਿਆ	
1	ਉਮਰ (ਸਾਲ):
2	ਲਿੰਗ: a) ਮਰਦ b) ਔਰਤ c) ਟਰਾਂਸਜੈਂਡਰ
3	ਵਿਆਹੁਤਾ ਸਥਿਤੀ: a) ਸਿੰਗਲ b) ਵਿਆਹੁਤਾ c) ਤਲਾਕਸ਼ੁਦਾ d) ਵਿਧਵਾ
4	ਰਿਹਾਇਸ਼: a) ਸ਼ਹਿਰੀ b) ਪੇਂਡੂ
5	ਪਰਿਵਾਰਕ ਮਾਸਿਕ ਆਮਦਨ (ਰੁਪਏ): a) <10000 b) 10001-20000 c) 20001-40000 d) 40001-60000 e) >60,000
6	ਵਿਦਿਅਕ ਸਥਿਤੀ: a) ਅਨਪੜ੍ਹ b) ਪ੍ਰਾਇਮਰੀ c) 10th d) 12ਵਾਂ e) ਗ੍ਰੈਜੂਏਟ ਅਤੇ ਉੱਚ
7	ਕਿੱਤਾ: a) ਵਿਦਿਆਰਥੀ b) ਬੇਰੁਜ਼ਗਾਰ c) ਘਰੇਲੂ ਔਰਤ d) ਸਰਕਾਰੀ ਕਰਮਚਾਰੀ e) ਨਿੱਜੀ ਨੌਕਰੀ f) ਕਾਰੋਬਾਰ

ਸੈਕਸ਼ਨ ਬੀ: ਕਾਸਮੈਟਿਕਸ ਦੀ ਵਰਤੋਂ ਅਤੇ ਮਾੜੀਆਂ ਘਟਨਾਵਾਂ ਬਾਰੇ ਗਿਆਨ

ਕ੍ਰਮ ਸੰਖਿਆ	
1	ਚਿਹਰੇ ਦੀ ਚਮੜੀ ਦੀ ਦੇਖਭਾਲ ਵਿੱਚ ਪਹਿਲਾ ਕਦਮ ਕੀ ਹੈ? a) ਮਾਇਸਚਰਾਈਜ਼ਰ b) ਕਲੀਨਜ਼ਰ ਮਿਲਕ c) ਟੋਨਰ d) ਪਤਾ ਨਹੀਂ
2	ਕਾਸਮੈਟਿਕ ਪਾਊਡਰ ਦੀ ਵਰਤੋਂ ਕਰਨ ਲਈ ਚਮੜੀ ਦੀ ਢੁਕਵੀਂ ਕਿਸਮ ਕਿਹੜੀ ਹੈ? a) ਤੇਲੀ ਚਮੜੀ b) ਸੰਵੇਦਨਸ਼ੀਲ ਚਮੜੀ c) ਖੁਸ਼ਕ ਚਮੜੀ d) ਪਤਾ ਨਹੀਂ
3	ਕਿਹੜਾ ਵਿਟਾਮਿਨ ਆਮ ਤੌਰ 'ਤੇ ਸਕਿਨਕੇਅਰ ਉਤਪਾਦਾਂ ਵਿੱਚ ਪਾਇਆ ਜਾਂਦਾ ਹੈ ਅਤੇ ਐਂਟੀਏਜਿੰਗ ਗੁਣਾਂ ਲਈ ਜਾਣਿਆ ਜਾਂਦਾ ਹੈ a) ਵਿਟਾਮਿਨ A b) ਵਿਟਾਮਿਨ B c) ਵਿਟਾਮਿਨ C d) ਪਤਾ ਨਹੀਂ
4	ਸੂਰਜ ਦੇ ਸੰਪਰਕ ਵਿੱਚ ਆਉਣ ਤੋਂ ਪਹਿਲਾਂ ਸਨਸਕ੍ਰੀਨ ਕਦੋਂ ਲਗਾਉਣੀ ਚਾਹੀਦੀ ਹੈ? a) ਸੂਰਜ ਦੇ ਸੰਪਰਕ ਵਿੱਚ ਆਉਣ ਤੋਂ 15-30 ਮਿੰਟ ਪਹਿਲਾਂ b) ਸੂਰਜ ਦੇ ਸੰਪਰਕ ਵਿੱਚ ਆਉਣ ਤੋਂ 1-2 ਘੰਟੇ ਪਹਿਲਾਂ c) ਇਸ ਨਾਲ ਕੋਈ ਫ਼ਰਕ ਨਹੀਂ ਪੈਂਦਾ ਕਿ ਤੁਸੀਂ ਸਨਸਕ੍ਰੀਨ ਕਦੋਂ ਲਗਾਉਂਦੇ ਹੋ d) ਪਤਾ ਨਹੀਂ
5	ਜ਼ਿਆਦਾਤਰ ਲਿੱਪ ਬਾਮ ਵਿੱਚ ਮੁੱਖ ਤੱਤ ਕੀ ਹੁੰਦੇ ਹਨ ਜੋ ਬੁੱਲ੍ਹਾਂ ਨੂੰ ਨਮੀ ਦੇਣ ਵਿੱਚ ਮਦਦ ਕਰਦੇ ਹਨ? a) ਮਧੂ ਮੱਖੀ ਮੋਮ b) ਪੈਟਰੋਲੀਅਮ ਜੈਲੀ c) ਨਾਰੀਅਲ ਤੇਲ d) ਪਤਾ ਨਹੀਂ
6	ਵਾਲਾਂ ਨੂੰ ਰੰਗਣ ਤੋਂ ਬਾਅਦ ਵਰਤਣ ਲਈ ਉਚਿਤ ਕੰਡੀਸ਼ਨਰ ਕੀ ਹੈ? a) ਨਿਯਮਿਤ ਵਾਲਾਂ ਦਾ ਕੰਡੀਸ਼ਨਰ b) ਡੀਪ ਮਾਸਕ c) ਹੇਅਰ ਜੈੱਲ d) ਪਤਾ ਨਹੀਂ
7	ਵਾਲਾਂ ਦੇ ਰੰਗਾਂ ਦਾ ਸਭ ਤੋਂ ਆਮ ਮਾੜਾ ਪ੍ਰਭਾਵ ਕੀ ਹੈ? a) ਸਿਕਰੀ b) ਤੇਲ ਵਿੱਚ ਵਾਧਾ c) ਝੁਰੜੀਆਂ d) ਪਤਾ ਨਹੀਂ
8	ਕਿਹੜੀ ਧਾਤ, ਜਦੋਂ ਕਾਸਮੈਟਿਕਸ ਵਿੱਚ ਉੱਚੇ ਪੱਧਰਾਂ ਵਿੱਚ ਮੌਜੂਦ ਹੁੰਦੀ ਹੈ, ਲੰਬੇ ਸਮੇਂ ਤੱਕ ਵਰਤੋਂ ਨਾਲ ਜ਼ਹਿਰੀਲੇਪਣ ਦਾ ਕਾਰਨ ਬਣ ਸਕਦੀ ਹੈ a) ਭਾਰੀ ਧਾਤ b) ਜ਼ਿੰਕ c) ਤਾਂਬਾ d) ਪਤਾ ਨਹੀਂ
9	ਕਿਹੜੇ ਕਾਸਮੈਟਿਕਸ ਚਮੜੀ ਦੇ ਕੈਂਸਰ ਦੇ ਖਤਰੇ ਨੂੰ ਘਟਾਉਣ ਵਿੱਚ ਮਦਦ ਕਰਦੇ ਹਨ? a) ਲਿਪਸਟਿਕ b) ਫਾਊਂਡੇਸ਼ਨ c) ਸਨਸਕ੍ਰੀਨ d) ਪਤਾ ਨਹੀਂ
10	ਕਾਸਮੈਟਿਕ-ਪ੍ਰੇਰਿਤ ਚਮੜੀ ਐਲਰਜੀ ਦਾ ਸਭ ਤੋਂ ਆਮ ਕਾਰਨ ਕੀ ਹੈ? a) ਪਰਫਿਊਮ ਵਿੱਚ ਖੁਸ਼ਬੂ b) ਮੇਕਅੱਪ ਵਿੱਚ ਨਕਲੀ ਰੰਗ c) ਮੋਇਸਚਰਾਈਜ਼ਰ ਵਿੱਚ ਇਮੋਲੀਐਂਟ d) ਪਤਾ ਨਹੀਂ
11	ਕਿਸ ਕਿਸਮ ਦੇ ਕਾਸਮੈਟਿਕਸ ਦੇ ਚਮੜੀ 'ਤੇ ਮਾੜੇ ਪ੍ਰਭਾਵ ਪੈਣ ਦੀ ਸਭ ਤੋਂ ਵੱਧ ਸੰਭਾਵਨਾ ਹੈ? a) ਪਾਣੀ ਅਧਾਰਤ ਕਾਸਮੈਟਿਕਸ b) ਤੇਲ-ਮੁਕਤ ਕਾਸਮੈਟਿਕਸ c) ਤੇਲ ਅਧਾਰਤ ਕਾਸਮੈਟਿਕਸ d) ਪਤਾ ਨਹੀਂ

ਸੈਕਸ਼ਨ ਸੀ: ਕਾਸਮੈਟਿਕਸ ਦੀ ਵਰਤੋਂ ਅਤੇ ਮਾੜੀਆਂ ਘਟਨਾਵਾਂ ਬਾਰੇ ਰਵੱਈਆ

ਕ੍ਰਮ ਸੰਖਿਆ	
1	ਕਾਸਮੈਟਿਕਸ ਦੀ ਅਣਉਚਿਤ ਵਰਤੋਂ ਝੁਰੜੀਆਂ, ਚਮੜੀ ਨੂੰ ਕਾਲਾ ਕਰਨ ਅਤੇ ਧੱਫੜ ਦਾ ਕਾਰਨ ਬਣ ਸਕਦੀ ਹੈ। 1. ਪੂਰੀ ਤਰ੍ਹਾਂ ਅਸਹਿਮਤ 2. ਅਸਹਿਮਤ 3. ਕੁਜ ਪਤਾ ਨਹੀ 4. ਸਹਿਮਤ 5. ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਹਿਮਤ
2	ਕਾਸਮੈਟਿਕਸ ਵਿੱਚ ਕੀਮਤ ਨਾਲੋਂ ਗੁਣਵੱਤਾ ਵਧੇਰੇ ਮਹੱਤਵਰੱਖਦੀ ਹੈ। 1. ਪੂਰੀ ਤਰ੍ਹਾਂ ਅਸਹਿਮਤ 2. ਅਸਹਿਮਤ 3. ਕੁਜ ਪਤਾ ਨਹੀ 4. ਸਹਿਮਤ 5. ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਹਿਮਤ
3	ਕੀ ਆਰਗੈਨਿਕ ਜੜ੍ਹੀ-ਬੂਟੀਆਂ ਨਾਲ ਬਣੇ ਕਾਸਮੈਟਿਕਸ ਸੁਰੱਖਿਅਤ ਅਤੇ ਸਿਹਤਮੰਦ ਹਨ? 1. ਪੂਰੀ ਤਰ੍ਹਾਂ ਅਸਹਿਮਤ 2. ਅਸਹਿਮਤ 3. ਕੁਜ ਪਤਾ ਨਹੀ 4. ਸਹਿਮਤ 5. ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਹਿਮਤ
4	ਕੀ ਟੈਟੂ ਕੈਂਸਰ ਦਾ ਕਾਰਨ ਬਣ ਸਕਦਾ ਹੈ? 1. ਪੂਰੀ ਤਰ੍ਹਾਂ ਅਸਹਿਮਤ 2. ਅਸਹਿਮਤ 3. ਕੁਜ ਪਤਾ ਨਹੀ 4. ਸਹਿਮਤ 5. ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਹਿਮਤ
5	ਸਲੇਟੀ ਵਾਲ ਕੈਮੀਕਲ ਵਾਲਾਂ ਦੇ ਰੰਗਾਂ ਅਤੇ ਬਲੀਚਿੰਗ ਦਾ ਮਾੜਾ ਪ੍ਰਭਾਵ ਹੋ ਸਕਦੇ ਹਨ। 1. ਪੂਰੀ ਤਰ੍ਹਾਂ ਅਸਹਿਮਤ 2. ਅਸਹਿਮਤ 3. ਕੁਜ ਪਤਾ ਨਹੀ 4. ਸਹਿਮਤ 5. ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਹਿਮਤ
6	ਛੋਟੀ ਉਮਰ ਤੋਂ ਹੀ ਸਨਸਕ੍ਰੀਨ ਦੀ ਵਰਤੋਂ ਸ਼ੁਰੂ ਕਰਨਾ ਮਹੱਤਵਪੂਰਨ ਹੈ। 1. ਪੂਰੀ ਤਰ੍ਹਾਂ ਅਸਹਿਮਤ 2. ਅਸਹਿਮਤ 3. ਕੁਜ ਪਤਾ ਨਹੀ 4. ਸਹਿਮਤ 5. ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਹਿਮਤ
7	ਆਮ ਤੌਰ ਤੇ ਮੇਕਅਪ ਨੂੰ ਹਟਾਉਣ ਲਈ ਪਾਣੀ ਦੀ ਵਰਤੋਂ ਕੀਤੀ ਜਾਂਦੀ ਹੈ । 1. ਪੂਰੀ ਤਰ੍ਹਾਂ ਅਸਹਿਮਤ 2. ਅਸਹਿਮਤ 3. ਕੁਜ ਪਤਾ ਨਹੀ 4. ਸਹਿਮਤ 5. ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਹਿਮਤ

INFORMED CONSENT DOCUMENT

Annexure IV

PARTICIPANT INFORMATION SHEET

I am Sweta Kumari, pursuing Ph. D in Lovely Professional University. I am doing a survey based research on cosmetic usage pattern and side effect occurs upon usage among the general population of Punjab. I am going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the study. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask me. This will take 5-10 minutes to fill.

Title of the Study/Project

To evaluate the cosmetic utilization pattern and adverse effects associated with it.

Purpose of the research

This study was aimed to assess cosmetics usage patterns and associated adverse reactions in the general public of the Jalandhar, Amritsar & Ludhiana.

Participant selection

Participants of any gender, aged 15- 50 years, using cosmetics will take part in this study

Procedures and protocol

This study will be conducted, from June 2021 to December 2021(may vary depending on covid situation), among the general population living in Jalandhar, Amritsar & Ludhiana district of Punjab. Study questionnaires will be distributed in public as well as at working places such as schools, colleges, hospitals, companies, and shopping malls.

Benefits

There may or may not be a direct benefit to you if you participate in this study but, this study will enhance our knowledge about the cosmetic utilization pattern and adverse reaction associated, so that possible applications for healthcare may be achieved in the future.

Risk

There is no risk involved in this study as only data will be collected from you.

Confidentiality of records

There will not be any identification by name. Only the investigators will know the results. Any personal information will not be shared with anyone without prior permission.

Voluntary Participation

Your participation in this research is entirely voluntary. You may also choose to not to participate in this study after reading this consent.

Reimbursements

You will not be provided any incentive to take part in the research.

Contact Information

If you have questions at any time about this study, you may contact to

Sweta kumari

Contact: 7488808116/8825117250

CONSENT

o I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. The investigator has explained the study in details and have clarified all my doubts. [ ]

o I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

o I agree to give consent for videography. [ ]

o I agree to give consent for photography. [ ]

o I agree to take part in the above study. [ ]

Signature of the Subject:

Date: / /

Signatory's Name----------

Signature of the Legally acceptable representative (In case of minor)

Date: / /

Signatory's Name:

Signature of the Investigator:

Date: / /

Annexure IV

सूचित सहमति प्रपत्र

मैं श्वेताकुमारी , लवली प्रोफेशनल विश्वविद्यालय से पीएच.डी कर रही हूँ। मैं कॉस्मेटिक उपयोग पैटर्न पर एक सर्वेक्षण आधारित शोध कर रही हूँ और पंजाब की सामान्य आबादी के बीच सौंदर्य उत्पाद के उपयोग के दुष्प्रभाव को अध्ययन कर रही हूँ । मैं आपको जानकारी देने जा रही हूँ और आपको इस शोध का हिस्सा बनने के लिए आमंत्रित करती हूँ । निर्णय लेने से पहले, आप किसी ऐसे व्यक्ति से बात कर सकते हैं जिसे आप अध्ययन के बारे में सहज महसूस करते हैं। इस सहमति फॉर्म में ऐसे शब्द हो सकते हैं जिन्हें आप नहीं समझते हैं। कृपया मुझे रुकने के लिए कहें क्योंकि हम जानकारी के माध्यम से जाते हैं और मुझे इसे समझाने में समय लगेगा। यदि बाद में आपके कोई प्रश्न हों, तो आप मुझसे पूछ सकते हैं। इसे भरने में 5-10 मिनट का समय लगेगा।

अध्ययन/परियोजना का शीर्षक

कॉस्मेटिक उपयोग पैटर्न और इससे जुड़े प्रतिकूल प्रभावों का मूल्यांकन करना।

शोध का उद्देश्य

इस अध्ययन का उद्देश्य जालंधर, अमृतसर और लुधियाना की आम जनता में सौंदर्य प्रसाधनों के उपयोग के पैटर्न और संबंधित प्रतिकूल प्रतिक्रियाओं का आकलन करना था।

प्रतिभागी चयन

सौंदर्य प्रसाधनों का उपयोग करने वाले 15-50 वर्ष की आयु के किसी भी लिंग के प्रतिभागी इस अध्ययन में भाग लेंगे ।

प्रक्रियाएं और प्रोटोकॉल

यह अध्ययन जून 2021 से दिसंबर 2021(भिन्न हो सकते हैं, यह कोविड की स्थिति पर निर्भर करता है) तक जालंधर, अमृतसर और लुधियाना में रहने वाली आम जनता के बीच आयोजित किया जाएगा । अध्ययन प्रश्नावलियों को सार्वजनिक और कार्यस्थलों जैसे स्कूलों, कॉलेजों, अस्पतालों, कंपनियों और शॉपिंग मॉल में वितरित किया जाएगा।

लाभ

यदि आप इस अध्ययन में भाग लेते हैं तो आपको प्रत्यक्ष लाभ हो भी सकता है और नहीं भी, लेकिन यह अध्ययन कॉस्मेटिक उपयोग पैटर्न और इससे जुड़ी प्रतिकूल प्रतिक्रिया के बारे में हमारे ज्ञान को बढ़ाएगा, ताकि भविष्य में स्वास्थ्य देखभाल के लिए संभावित अनुप्रयोगों को प्राप्त किया जा सके।

जोखिम

इस अध्ययन में कोई जोखिम शामिल नहीं है क्योंकि केवल आपसे डेटा एकत्र किया जाएगा।

अभिलेखों की गोपनीयता

नाम से कोई पहचान नहीं होगी। केवल जांचकर्ता ही परिणाम जान पाएंगे। कोई भी व्यक्तिगत जानकारी बिना पूर्व अनुमति के किसी के साथ साझा नहीं की जाएगी।

स्वैच्छिक भागीदारी

इस शोध में आपकी भागीदारी पूर्णतः स्वैच्छिक है। आप इस सहमति पत्र को पढ़ने के बाद इस अध्ययन में भाग न लेने का विकल्प भी चुन सकते हैं।

पैसे की वापसी

आपको शोध में भाग लेने के लिए कोई प्रोत्साहन प्रदान नहीं किया जाएगा।

संपर्क जानकारी

यदि आप इस अध्ययन के बारे में किसी भी समय कोई प्रश्न पूछना चाहते हैं, तो आप श्वेता कुमारी से संपर्क कर सकते हैं।

संपर्क करें: 7488808116/8825117250

सहमति

o मैं पुष्टि करती/ करता हूँ कि मैंने उपरोक्त अध्ययन के लिए सूचना पत्रक को पढ़ और समझ लिया है और मुझे प्रश्न पूछने का अवसर मिला है। अन्वेषक ने अध्ययन को विस्तार से समझाया है और मेरे सभी संदेहों को स्पष्ट किया है। [ ]

मैं सहमत हूं कि इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं किया जाएगा, बशर्ते ऐसा उपयोग केवल वैज्ञानिक/ शैक्षनिक उद्देश्यों के लिए हो। [ ]

मैं वीडियोग्राफी के लिए सहमति देने के लिए सहमत हूँ। [ ]

मैं फोटोग्राफी के लिए सहमति देने के लिए सहमत हूँ। [ ]

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ। [ ]

प्रतिभागी के हस्ताक्षर:

दिनांक: / /

हस्ताक्षरकर्ता का नाम

कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (नाबालिग के मामले में)

दिनांक: / /

हस्ताक्षरकर्ता का नाम:

अन्वेषक के हस्ताक्षर:

दिनांक: / / अन्वेषक का नाम:

Annexure IV

ਸੂਚਿਤ ਸਹਿਮਤੀ ਫਾਰਮ

ਮੈਂ ਸਵੇਤਾ ਕੁਮਾਰੀ ਹਾਂ, ਮੈਂ ਲਵਲੀ ਪ੍ਰੋਫੈਸ਼ਨਲ ਯੂਨੀਵਰਸਿਟੀ ਤੋਂ ਪੀਐਚਡੀ ਕਰ ਰਹੀ ਹਾਂ। ਮੈਂ ਕਾਸਮੈਟਿਕ ਵਰਤੋਂ ਦੇ ਪੈਟਰਨ 'ਤੇ ਇੱਕ ਸਰਵੇਖਣ ਅਧਾਰਤ ਖੋਜ ਕਰ ਰਹੀ ਹਾਂ ਅਤੇ ਪੰਜਾਬ ਦੀ ਆਮ ਆਬਾਦੀ ਵਿੱਚ ਵਰਤੋਂ 'ਤੇ ਮਾੜੇ ਪ੍ਰਭਾਵ ਹੁੰਦੇ ਹਨ। ਮੈਂ ਤੁਹਾਨੂੰ ਜਾਣਕਾਰੀ ਦੇਣ ਜਾ ਰਹੀ ਹਾਂ ਅਤੇ ਤੁਹਾਨੂੰ ਇਸ ਖੋਜ ਦਾ ਹਿੱਸਾ ਬਣਨ ਲਈ ਸੱਦਾ ਦੇਣ ਜਾ ਰਹੀ ਹਾਂ। ਇਸ ਤੋਂ ਪਹਿਲਾਂ ਕਿ ਤੁਸੀਂ ਫੈਸਲਾ ਕਰੋ, ਤੁਸੀਂ ਕਿਸੇ ਵੀ ਅਜਿਹੇ ਵਿਅਕਤੀ ਨਾਲ ਗੱਲ ਕਰ ਸਕਦੇ ਹੋ ਜਿਸ ਨਾਲ ਤੁਸੀਂ ਅਧਿਐਨ ਬਾਰੇ ਸਹਿਜ ਮਹਿਸੂਸ ਕਰਦੇ ਹੋ। ਇਸ ਸਹਿਮਤੀ ਫਾਰਮ ਵਿੱਚ ਉਹ ਸ਼ਬਦ ਹੋ ਸਕਦੇ ਹਨ ਜੋ ਤੁਸੀਂ ਨਹੀਂ ਸਮਝਦੇ। ਕਿਰਪਾ ਕਰਕੇ ਮੈਨੂੰ ਰੁਕਣ ਲਈ ਕਹੋ ਕਿਉਂਕਿ ਅਸੀਂ ਜਾਣਕਾਰੀ ਨੂੰ ਪੜ੍ਹਦੇ ਹਾਂ ਅਤੇ ਮੈਨੂੰ ਸਮਝਾਉਣ ਲਈ ਸਮਾਂ ਲੱਗੇਗਾ। ਜੇ ਬਾਅਦ ਵਿੱਚ ਤੁਹਾਡੇ ਕੋਈ ਸਵਾਲ ਹਨ, ਤਾਂ ਤੁਸੀਂ ਮੈਨੂੰ ਪੁੱਛ ਸਕਦੇ ਹੋ। ਇਸ ਨੂੰ ਭਰਨ ਵਿੱਚ 5-10 ਮਿੰਟ ਲੱਗਣਗੇ।

ਅਧਿਐਨ/ਪ੍ਰੋਜੈਕਟ ਦਾ ਸਿਰਲੇਖ

ਕਾਸਮੈਟਿਕ ਵਰਤੋਂ ਦੇ ਪੈਟਰਨ ਅਤੇ ਇਸ ਨਾਲ ਜੁੜੇ ਮਾੜੇ ਪ੍ਰਭਾਵਾਂ ਦਾ ਮੁਲਾਂਕਣ ਕਰਨਾ।

ਖੋਜ ਦਾ ਮਕਸਦ

ਇਸ ਅਧਿਐਨ ਦਾ ਉਦੇਸ਼ ਜਲੰਧਰ, ਅੰਮ੍ਰਿਤਸਰ ਅਤੇ ਲੁਧਿਆਣਾ ਦੇ ਆਮ ਲੋਕਾਂ ਵਿੱਚ ਕਾਸਮੈਟਿਕਸ ਦੀ ਵਰਤੋਂ ਦੇ ਤਰੀਕਿਆਂ ਅਤੇ ਇਸ ਨਾਲ ਜੁੜੀਆਂ ਮਾੜੀਆਂ ਪ੍ਰਤੀਕਿਰਿਆਵਾਂ ਦਾ ਮੁਲਾਂਕਣ ਕਰਨਾ ਸੀ।

ਭਾਗੀਦਾਰ ਦੀ ਚੋਣ

ਕਾਸਮੈਟਿਕਸ ਦੀ ਵਰਤੋਂ ਕਰਨ ਵਾਲੇ 15-50 ਸਾਲ ਦੀ ਉਮਰ ਦੇ ਕਿਸੇ ਵੀ ਲਿੰਗ ਦੇ ਭਾਗੀਦਾਰ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣਗੇ ।

ਪ੍ਰਕਿਰਿਆਵਾਂ ਅਤੇ ਪ੍ਰੋਟੋਕੋਲ

ਇਹ ਅਧਿਐਨ ਜੂਨ 2021 ਤੋਂ ਦਸੰਬਰ 2021 ਤੱਕ ਪੰਜਾਬ ਦੇ ਜਲੰਧਰ, ਅੰਮ੍ਰਿਤਸਰ ਅਤੇ ਲੁਧਿਆਣਾ ਜ਼ਿਲ੍ਹਿਆਂ ਵਿੱਚ ਰਹਿਣ ਵਾਲੀ ਆਮ ਆਬਾਦੀ ਵਿੱਚ (ਕੋਵਿਡ ਦੀ ਸਥਿਤੀ ਦੇ ਅਧਾਰ ਤੇ ਵੱਖ-ਵੱਖ ਹੋ ਸਕਦਾ ਹੈ) ਕੀਤਾ ਜਾਵੇਗਾ। ਅਧਿਐਨ ਪ੍ਰਸ਼ਨਾਵਲੀਆਂ ਜਨਤਕ ਤੌਰ 'ਤੇ ਅਤੇ ਨਾਲ ਹੀ ਕੰਮ ਕਾਜੀ ਥਾਵਾਂ ਜਿਵੇਂ ਕਿ ਸਕੂਲਾਂ, ਕਾਲਜਾਂ, ਹਸਪਤਾਲਾਂ, ਕੰਪਨੀਆਂ ਅਤੇ ਸ਼ਾਪਿੰਗ ਮਾਲਾਂ ਵਿਖੇ ਵੰਡੀਆਂ ਜਾਣਗੀਆਂ।

ਲਾਭ

ਜੇ ਤੁਸੀਂ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਂਦੇ ਹੋ ਤਾਂ ਤੁਹਾਡੇ ਲਈ ਸਿੱਧਾ ਲਾਭ ਹੋ ਸਕਦਾ ਹੈ ਜਾ ਨਹੀਂ ਵੀ ਹੋ ਸਕਦਾ ਹੈ ਪਰ, ਇਹ ਅਧਿਐਨ ਕਾਸਮੈਟਿਕ ਵਰਤੋਂ ਦੇ ਪੈਟਰਨ ਅਤੇ ਸੰਬੰਧਿਤ ਉਲਟ ਪ੍ਰਤੀਕਿਰਿਆ ਬਾਰੇ ਸਾਡੇ ਗਿਆਨ ਨੂੰ ਵਧਾਏਗਾ, ਤਾਂ ਜੋ ਭਵਿੱਖ ਵਿੱਚ ਸਿਹਤ ਸੰਭਾਲ ਵਾਸਤੇ ਸੰਭਾਵਿਤ ਐਪਲੀਕੇਸ਼ਨਾਂ ਪ੍ਰਾਪਤ ਕੀਤੀਆਂ ਜਾ ਸਕਣ।

ਜੋਖਮ

ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਕੋਈ ਜੋਖਮ ਸ਼ਾਮਲ ਨਹੀਂ ਹੈ ਕਿਉਂਕਿ ਕੇਵਲ ਡੇਟਾ ਤੁਹਾਡੇ ਕੋਲੋਂ ਇਕੱਤਰ ਕੀਤਾ ਜਾਵੇਗਾ।

ਰਿਕਾਰਡਾ ਦੀ ਗੁਪਤਤਾ

ਨਾਮ ਦੁਆਰਾ ਕੋਈ ਪਛਾਣ ਨਹੀਂ ਹੋਵੇਗੀ। ਸਿਰਫ ਜਾਚਕਰਤਾਵਾ ਨੂੰ ਹੀ ਨਤੀਜੇ ਪਤਾ ਹੋਣਗੇ। ਕਿਸੇ ਵੀ ਨਿੱਜੀ ਜਾਣਕਾਰੀ ਨੂੰ ਬਿਨਾ ਅਗਾਊਂ ਇਜਾਜ਼ਤ ਦੇ ਕਿਸੇ ਨਾਲ ਸਾਝਾ ਨਹੀਂ ਕੀਤਾ ਜਾਵੇਗਾ।

ਸਵੈ-ਇੱਛਤ ਭਾਗੀਦਾਰੀ

ਇਸ ਖੋਜ ਵਿੱਚ ਤੁਹਾਡੀ ਭਾਗੀਦਾਰੀ ਪੂਰੀ ਤਰ੍ਹਾ ਸਵੈ-ਇੱਛਤ ਹੈ। ਇਸ ਸਹਿਮਤੀ ਨੂੰ ਪੜ੍ਹਨ ਤੋਂ ਬਾਅਦ ਤੁਸੀਂ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਨਾ ਲੈਣ ਦੀ ਚੋਣ ਵੀ ਕਰ ਸਕਦੇ ਹੋ।

ਮੁਆਵਜ਼ੇ

ਤੁਹਾਨੂੰ ਖੋਜ ਵਿੱਚ ਭਾਗ ਲੈਣ ਲਈ ਕੋਈ ਉਤਸ਼ਾਹ ਪ੍ਰਦਾਨ ਨਹੀਂ ਕੀਤਾ ਜਾਵੇਗਾ।

ਸੰਪਰਕ ਜਾਣਕਾਰੀ

ਜੇ ਇਸ ਅਧਿਐਨ ਬਾਰੇ ਕਿਸੇ ਵੀ ਸਮੇਂ ਤੁਹਾਡੇ ਕੋਈ ਸਵਾਲ ਹਨ, ਤਾ ਤੁਸੀਂ

ਸਵੇਤਾ ਕੁਮਾਰੀ ਨਾਲ ਸੰਪਰਕ ਕਰ ਸਕਦੇ ਹੋ
ਸੰਪਰਕ: 7488808116/8825117250

ਸਹਿਮਤੀ

- ਮੈ ਪੁਸ਼ਟੀ ਕਰਦਾ ਹਾ/ ਕਰਦੀ ਹਾ ਕਿ ਮੈ ਉਪਰੋਕਤ ਅਧਿਐਨ ਵਾਸਤੇ ਜਾਣਕਾਰੀ ਸ਼ੀਟ ਨੂੰ ਪੜ੍ਹ ਲਿਆ ਹੈ ਅਤੇ ਸਮਝ ਲਿਆ ਹੈ ਅਤੇ ਮੈਨੂੰ ਸਵਾਲ ਪੁੱਛਣ ਦਾ ਮੌਕਾ ਮਿਲਿਆ ਹੈ। ਜਾਚਕਰਤਾ ਨੇ ਅਧਿਐਨ ਨੂੰ ਵਿਸਥਾਰ ਵਿੱਚ ਸਮਝਾਇਆ ਹੈ ਅਤੇ ਮੇਰੇ ਸਾਰੇ ਸ਼ੰਕਾ ਨੂੰ ਸਪੱਸ਼ਟ ਕੀਤਾ ਹੈ। [ ]
- ਮੈ ਇਸ ਅਧਿਐਨ ਤੋਂ ਪੈਦਾ ਹੋਣ ਵਾਲੇ ਕਿਸੇ ਵੀ ਡੇਟਾ ਜਾ ਨਤੀਜਿਆ ਦੀ ਵਰਤੋਂ ਨੂੰ ਸੀਮਤ ਨਾ ਕਰਨ ਲਈ ਸਹਿਮਤ ਹਾ ਬਸ਼ਰਤੇ ਅਜਿਹੀ ਵਰਤੋਂ ਕੇਵਲ ਵਿਗਿਆਨਕ ਉਦੇਸ਼(ਵਾ) ਲਈ ਹੋਵੇ। [ ]
- ਮੈ ਵੀਡੀਓਰਿਗ੍ਰਾਫੀ ਲਈ ਸਹਿਮਤੀ ਦੇਣ ਲਈ ਸਹਿਮਤ ਹਾ। [ ]
- ਮੈ ਫੋਟੋਗ੍ਰਾਫੀ ਲਈ ਸਹਿਮਤੀ ਦੇਣ ਲਈ ਸਹਿਮਤ ਹਾ। [ ]
- ਮੈ ਉਪਰੋਕਤ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਲਈ ਸਹਿਮਤ ਹਾ। [ ]

ਪਾਤਰ ਦੇ ਦਸਤਖਤ:
ਮਿਤੀ:_____/_____/_____
ਹਸਤਾਖਰ ਕਰਨ ਵਾਲੇ ਦਾ ਨਾਮ—
_____

ਕਾਨੂੰਨੀ ਤੌਰ 'ਤੇ ਸਵੀਕਾਰਯੋਗ ਪ੍ਰਤੀਨਿਧੀ ਦੇ ਦਸਤਖਤ
(ਨਾਬਾਲਗ ਦੇ ਮਾਮਲੇ ਵਿੱਚ)

ਮਿਤੀ:_____/_____/_____
ਹਸਤਾਖਰ ਕਰਨ ਵਾਲੇ ਦਾ
ਨਾਮ:_____

ਜਾਚਕਰਤਾ ਦੇ ਦਸਤਖਤ: ਮਿਤੀ:
_____/_____/_____
ਜਾਚਕਰਤਾ ਦਾ ਨਾਮ

Annexure IV

Participant Inforation Sheet

I am Sweta Kumari, pursuing Ph. D in Lovely Professional University. I am doing a survey based research on assessment of knowledge and attitude regarding cosmetic utilization and associated adverse events among the general population of Punjab. I am going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the study. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask me. This will take 5-10 minutes to fill.

Title of the Study/Project

The aim of the study is to assess the knowledge and attitude regarding cosmetic utilization and associated adverse events

Purpose of the research

The aim of study is to assess the knowledge and attitude regarding cosmetic utilization and associated adverse events in the general public of the Jalandhar, Amritsar & Ludhiana.

Participant selection

Participants of any gender, aged 18- 50 years, using cosmetics will take part in this study

Procedures and protocol

This study will be conducted, for 3-6 months, among the general population living in Jalandhar, Amritsar & Ludhiana district of Punjab. Study questionnaires will be distributed in public as well as at working places such as schools, colleges, hospitals, companies, and shopping malls.

Benefits

There may or may not be a direct benefit to you if you participate in this study but, this study will enhance our knowledge about the cosmetic utilization pattern and adverse events associated, so that possible applications for healthcare may be achieved in the future.

Risk

There is no risk involved in this study as only data will be collected from you.

Confidentiality of records

There will not be any identification by name. Only the investigators will know the results. Any personal information will not be shared with anyone without prior permission.

Voluntary Participation

Your participation in this research is entirely voluntary. You may also choose to not to participate in this study after reading this consent.

Reimbursements

You will not be provided any incentive to take part in the research.

Contact Information

If you have questions at any time about this study, you may contact to

Sweta kumari

Contact: 8825117250

CONSENT

o I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. The investigator have explained the study in details and have clarified all my doubts. [ ]

o I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

o I agree to take part in the above study. [ ]

Signature of the Subject:

Date: / /

Signatory's Name----------

Signature of the Investigator:

Date: / /

Name of the Investigator

Annexure IV

सूचित सहमति प्रपत्र

मैं श्वेताकुमारी , लवली प्रोफेशनल विश्वविद्यालय से पीएच.डी कर रही हूँ। मैं पंजाब की सामान्य आबादी के बीच सौंदर्य उपयोग और संबंधित हानिकारक घटनाओं के सम्बंध में ज्ञान और दृष्टिकोण का मूल्यांकन करने के लिए एक सर्वेक्षण पर आधारित अनुसंधान कर रही हूँ । मैं आपको जानकारी देने जा रही हूँ और आपको इस शोध का हिस्सा बनने के लिए आमंत्रित करती हूँ । निर्णय लेने से पहले, आप किसी ऐसे व्यक्ति से बात कर सकते हैं जिसे आप अध्ययन के बारे में सहज महसूस करते हैं। इस सहमति फॉर्म में ऐसे शब्द हो सकते हैं जिन्हें आप नहीं समझते हैं। कृपया मुझे रुकने के लिए कहें क्योंकि हम जानकारी के माध्यम से जाते हैं और मुझे इसे समझाने में समय लगेगा। यदि बाद में आपके कोई प्रश्न हों, तो आप मुझसे पूछ सकते हैं। इसे भरने में 5-10 मिनट का समय लगेगा।

अध्ययन/परियोजना का शीर्षक

अध्ययन का उद्देश्य सौंदर्य उपयोग और संबंधित हानिकारक घटनाओं के सम्बंध में ज्ञान और दृष्टिकोण का मूल्यांकन करना है।

शोध का उद्देश्य

इस अध्ययन का उद्देश्य जालंधर, अमृतसर और लुधियाना की आम जनता में सौंदर्य उपयोग और संबंधित हानिकारक घटनाओं के सम्बंध में ज्ञान और दृष्टिकोण का मूल्यांकन करना है।

प्रतिभागी चयन

सौंदर्य प्रसाधनों का उपयोग करने वाले 18-50 वर्ष की आयु के किसी भी लिंग के प्रतिभागी इस अध्ययन में भाग लेंगे ।

प्रक्रियाएं और प्रोटोकॉल

यह अध्ययन 3-6 months, तक जालंधर, अमृतसर और लुधियाना में रहने वाली आम जनता के बीच आयोजित किया जाएगा । अध्ययन प्रश्नावलियों को सार्वजनिक और कार्यस्थलों जैसे स्कूलों, कॉलेजों, अस्पतालों, कंपनियों और शॉपिंग मॉल में वितरित किया जाएगा।

लाभ

यदि आप इस अध्ययन में भाग लेते हैं तो आपको प्रत्यक्ष लाभ हो भी सकता है और नहीं भी, लेकिन यह अध्ययन हमारे सौंदर्य उपयोग पैटर्न और संबंधित हानिकारक घटनाओं के बारे में हमारे ज्ञान को बढ़ावा देगा, ताकि भविष्य में स्वास्थ्य से संबंधित संभावित अनुप्रयोग हो ।

जोखिम

इस अध्ययन में कोई जोखिम शामिल नहीं है क्योंकि केवल आपसे डेटा एकत्र किया जाएगा।

अभिलेखों की गोपनीयता

नाम से कोई पहचान नहीं होगी। केवल जांचकर्ता ही परिणाम जान पाएंगे। कोई भी व्यक्तिगत जानकारी बिना पूर्व अनुमति के किसी के साथ साझा नहीं की जाएगी।

स्वैच्छिक भागीदारी

इस शोध में आपकी भागीदारी पूर्णतः स्वैच्छिक है। आप इस सहमति पत्र को पढ़ने के बाद इस अध्ययन में भाग न लेने का विकल्प भी चुन सकते हैं।

पैसे की वापसी

आपको शोध में भाग लेने के लिए कोई प्रोत्साहन प्रदान नहीं किया जाएगा।

संपर्क जानकारी

यदि आप इस अध्ययन के बारे में किसी भी समय कोई प्रश्न पूछना चाहते हैं, तो आप श्वेता कुमारी से संपर्क कर सकते हैं।

संपर्क करें: 8825117250

सहमति

o मैं पुष्टि करती/ करता हूँ कि मैंने उपरोक्त अध्ययन के लिए सूचना पत्रक को पढ़ और समझ लिया है और मुझे प्रश्न पूछने का अवसर मिला है। अन्वेषक ने अध्ययन को विस्तार से समझाया है और मेरे सभी संदेहों को स्पष्ट किया है। [ ]

मैं सहमत हूं कि इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं किया जाएगा, बशर्ते ऐसा उपयोग केवल वैज्ञानिक/ शैक्षनिक उद्देश्यों के लिए हो। [ ]

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ। [ ]

प्रतिभागी के हस्ताक्षर:

दिनांक: / /

हस्ताक्षरकर्ता का नाम

अन्वेषक के हस्ताक्षर:

दिनांक: / /

अन्वेषक का नाम:

Annexure IV

ਸੂਚਿਤ ਸਹਿਮਤੀ ਫਾਰਮ

ਮੈਂ ਸਵੇਤਾ ਕੁਮਾਰੀ ਹਾਂ, ਜੋ ਲਵਲੀ ਪ੍ਰੋਫੈਸ਼ਨਲ ਯੂਨੀਵਰਸਿਟੀ ਤੋਂ ਪੀਐਚਡੀ ਕਰ ਰਹੀ ਹਾਂ। ਮੈਂ ਪੰਜਾਬ ਦੀ ਆਮ ਆਬਾਦੀ ਵਿੱਚ ਕਾਸਮੈਟਿਕ ਦੀ ਵਰਤੋਂ ਅਤੇ ਇਸ ਨਾਲ ਜੁੜੀਆਂ ਮਾੜੀਆਂ ਘਟਨਾਵਾਂ ਬਾਰੇ ਗਿਆਨ ਅਤੇ ਰਵੱਈਏ ਦੇ ਮੁਲਾਂਕਣ ਬਾਰੇ ਇੱਕ ਸਰਵੇਖਣ ਆਧਾਰਤ ਖੋਜ ਕਰ ਰਹੀ ਹਾਂ। ਮੈਂ ਤੁਹਾਨੂੰ ਜਾਣਕਾਰੀ ਦੇਣ ਜਾ ਰਹੀ ਹਾਂ ਅਤੇ ਤੁਹਾਨੂੰ ਇਸ ਖੋਜ ਦਾ ਹਿੱਸਾ ਬਣਨ ਲਈ ਸੱਦਾ ਦੇਣ ਜਾ ਰਹੀ ਹਾਂ। ਇਸ ਤੋਂ ਪਹਿਲਾਂ ਕਿ ਤੁਸੀਂ ਫੈਸਲਾ ਕਰੋ, ਤੁਸੀਂ ਕਿਸੇ ਵੀ ਅਜਿਹੇ ਵਿਅਕਤੀ ਨਾਲ ਗੱਲ ਕਰ ਸਕਦੇ ਹੋ ਜਿਸ ਨਾਲ ਤੁਸੀਂ ਅਧਿਐਨ ਬਾਰੇ ਸਹਿਜ ਮਹਿਸੂਸ ਕਰਦੇ ਹੋ। ਇਸ ਸਹਿਮਤੀ ਫਾਰਮ ਵਿੱਚ ਉਹ ਸ਼ਬਦ ਹੋ ਸਕਦੇ ਹਨ ਜੋ ਤੁਸੀਂ ਨਹੀਂ ਸਮਝਦੇ। ਕਿਰਪਾ ਕਰਕੇ ਮੈਨੂੰ ਰੁਕਣ ਲਈ ਕਹੋ ਕਿਉਂਕਿ ਅਸੀਂ ਜਾਣਕਾਰੀ ਨੂੰ ਪੜ੍ਹਦੇ ਹਾਂ ਅਤੇ ਮੈਨੂੰ ਵਿਆਖਿਆ ਕਰਨ ਲਈ ਸਮਾਂ ਲੱਗੇਗਾ। ਜੇ ਬਾਅਦ ਵਿੱਚ ਤੁਹਾਡੇ ਕੋਈ ਸਵਾਲ ਹਨ, ਤਾਂ ਤੁਸੀਂ ਮੈਨੂੰ ਪੁੱਛ ਸਕਦੇ ਹੋ। ਇਸ ਨੂੰ ਭਰਨ ਵਿੱਚ 5-10 ਮਿੰਟ ਲੱਗਣਗੇ।

ਅਧਿਐਨ/ਪ੍ਰੋਜੈਕਟ ਦਾ ਸਿਰਲੇਖ
ਇਸ ਅਧਿਐਨ ਦਾ ਉਦੇਸ਼ ਕਾਸਮੈਟਿਕ ਵਰਤੋਂ ਅਤੇ ਸੰਬੰਧਿਤ ਮਾੜੀਆਂ ਘਟਨਾਵਾਂ ਬਾਰੇ ਗਿਆਨ ਅਤੇ ਰਵੱਈਏ ਦਾ ਮੁਲਾਂਕਣ ਕਰਨਾ ਹੈ।

ਖੋਜ ਦਾ ਮਕਸਦ

ਇਸ ਅਧਿਐਨ ਦਾ ਉਦੇਸ਼ ਜਲੰਧਰ, ਅੰਮ੍ਰਿਤਸਰ ਅਤੇ ਲੁਧਿਆਣਾ ਦੇ ਆਮ ਲੋਕਾਂ ਵਿੱਚ ਕਾਸਮੈਟਿਕ ਦੀ ਵਰਤੋਂ ਅਤੇ ਇਸ ਨਾਲ ਜੁੜੀਆਂ ਮਾੜੀਆਂ ਘਟਨਾਵਾਂ ਬਾਰੇ ਗਿਆਨ ਅਤੇ ਰਵੱਈਏ ਦਾ ਮੁਲਾਂਕਣ ਕਰਨਾ ਹੈ।

ਭਾਗੀਦਾਰ ਦੀ ਚੋਣ

ਕਾਸਮੈਟਿਕਸ ਦੀ ਵਰਤੋਂ ਕਰਨ ਵਾਲੇ 18-50 ਸਾਲ ਦੀ ਉਮਰ ਦੇ ਕਿਸੇ ਵੀ ਲਿੰਗ ਦੇ ਭਾਗੀਦਾਰ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣਗੇ।

ਪ੍ਰਕਿਰਿਆਵਾਂ ਅਤੇ ਪ੍ਰੋਟੋਕੋਲ

ਇਹ ਅਧਿਐਨ ਪੰਜਾਬ ਦੇ ਜਲੰਧਰ, ਅੰਮ੍ਰਿਤਸਰ ਅਤੇ ਲੁਧਿਆਣਾ ਜ਼ਿਲ੍ਹਿਆਂ ਵਿੱਚ ਰਹਿਣ ਵਾਲੀ ਆਮ ਆਬਾਦੀ ਵਿੱਚ 3-6 ਮਹੀਨਿਆਂ ਲਈ ਕੀਤਾ ਜਾਵੇਗਾ। ਅਧਿਐਨ ਪ੍ਰਸ਼ਨਾਵਲੀਆਂ ਜਨਤਕ ਤੌਰ ਤੇ ਅਤੇ ਨਾਲ ਹੀ ਕੰਮ ਵਾਲੀ ਥਾਵਾਂ ਜਿਵੇਂ ਕਿ ਸਕੂਲਾਂ, ਕਾਲਜਾਂ, ਹਸਪਤਾਲਾਂ, ਕੰਪਨੀਆਂ ਅਤੇ ਸ਼ਾਪਿੰਗ ਮਾਲਾਂ ਵਿਖੇ ਵੰਡੀਆਂ ਜਾਣਗੀਆਂ।

ਲਾਭ

ਜੇ ਤੁਸੀਂ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਂਦੇ ਹੋ ਤਾਂ ਤੁਹਾਡੇ ਲਈ ਸਿੱਧਾ ਲਾਭ ਹੋ ਸਕਦਾ ਹੈ ਜਾਂ ਨਹੀਂ ਵੀ ਹੋ ਸਕਦਾ ਹੈ ਪਰ, ਇਹ ਅਧਿਐਨ ਕਾਸਮੈਟਿਕ ਵਰਤੋਂ ਦੇ ਪੈਟਰਨ ਅਤੇ ਇਸ ਨਾਲ ਜੁੜੀਆਂ ਮਾੜੀਆਂ ਘਟਨਾਵਾਂ ਬਾਰੇ ਸਾਡੇ ਗਿਆਨ ਨੂੰ ਵਧਾਏਗਾ, ਤਾਂ ਜੋ ਭਵਿੱਖ ਵਿੱਚ ਸਿਹਤ ਸੰਭਾਲ ਵਾਸਤੇ ਸੰਭਾਵਿਤ ਐਪਲੀਕੇਸ਼ਨਾਂ ਪ੍ਰਾਪਤ ਕੀਤੀਆਂ ਜਾ ਸਕਣ।

ਜੋਖਮ

ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਕੋਈ ਜੋਖਮ ਸ਼ਾਮਲ ਨਹੀਂ ਹੈ ਕਿਉਂਕਿ ਕੋਵਲ ਡੇਟਾ ਤੁਹਾਡੇ ਕੋਲੋਂ ਇਕੱਤਰ ਕੀਤਾ ਜਾਵੇਗਾ।

ਰਿਕਾਰਡਾਂ ਦੀ ਗੁਪਤਤਾ

ਨਾਮ ਦੁਆਰਾ ਕੋਈ ਪਛਾਣ ਨਹੀਂ ਹੋਵੇਗੀ। ਸਿਰਫ ਜਾਂਚਕਰਤਾਵਾਂ ਨੂੰ ਹੀ ਨਤੀਜੇ ਪਤਾ ਹੋਣਗੇ। ਕਿਸੇ ਵੀ ਨਿੱਜੀ ਜਾਣਕਾਰੀ ਨੂੰ ਬਿਨਾਂ ਅਗਾਊਂ ਇਜਾਜ਼ਤ ਦੇ ਕਿਸੇ ਨਾਲ ਸਾਂਝਾ ਨਹੀਂ ਕੀਤਾ ਜਾਵੇਗਾ।

ਸਵੈਇੱਛਤ ਭਾਗੀਦਾਰੀ

ਇਸ ਖੋਜ ਵਿੱਚ ਤੁਹਾਡੀ ਭਾਗੀਦਾਰੀ ਪੂਰੀ ਤਰ੍ਹਾਂ ਸਵੈ-ਇੱਛਤ ਹੈ।ਇਸ ਸਹਿਮਤੀ ਨੂੰ ਪੜ੍ਹਨ ਤੋਂ ਬਾਅਦ ਤੁਸੀਂ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਨਾ ਲੈਣ ਦੀ ਚੋਣ ਵੀ ਕਰ ਸਕਦੇ ਹੋ।

ਮੁਆਵਜ਼ੇ

ਤੁਹਾਨੂੰ ਖੋਜ ਵਿੱਚ ਭਾਗ ਲੈਣ ਲਈ ਕੋਈ ਪ੍ਰੋਤਸਾਹਨ ਪ੍ਰਦਾਨ ਨਹੀਂ ਕੀਤਾ ਜਾਵੇਗਾ।

ਸੰਪਰਕ ਜਾਣਕਾਰੀ

ਜੇ ਇਸ ਅਧਿਐਨ ਬਾਰੇ ਕਿਸੇ ਵੀ ਸਮੇਂ ਤੁਹਾਡੇ ਕੋਈ ਸਵਾਲ ਹਨ, ਤਾਂ ਤੁਸੀਂ ਸਵੇਤਾ ਕੁਮਾਰੀ ਨਾਲ

ਸੰਪਰਕ ਕਰ ਸਕਦੇ ਹੋ

ਸੰਪਰਕ: 8825117250

ਸਹਿਮਤੀ

- ਮੈਂ ਪੁਸ਼ਟੀ ਕਰਦਾ/ ਕਰਦੀ ਹਾਂ ਕਿ ਮੈਂ ਉਪਰੋਕਤ ਅਧਿਐਨ ਦਾਸਤੇ ਜਾਣਕਾਰੀ ਸ਼ੀਟ ਨੂੰ ਪੜ੍ਹ ਲਿਆ ਹੈ ਅਤੇ ਸਮਝ ਲਿਆ ਹੈ ਅਤੇ ਮੈਨੂੰ ਸਵਾਲ ਪੁੱਛਣ ਦਾ ਮੌਕਾ ਮਿਲਿਆ ਹੈ। ਜਾਂਚਕਰਤਾ ਨੇ ਅਧਿਐਨ ਨੂੰ ਵਿਸਥਾਰ ਵਿੱਚ ਸਮਝਾਇਆ ਹੈ ਅਤੇ ਮੇਰੇ ਸਾਰੇ ਸ਼ੰਕਾ ਨੂੰ ਸਪੱਸ਼ਟ ਕੀਤਾ ਹੈ। [ ]
- ਮੈਂ ਇਸ ਅਧਿਐਨ ਤੋਂ ਪੈਦਾ ਹੋਣ ਵਾਲੇ ਕਿਸੇ ਵੀ ਡੇਟਾ ਜਾਂ ਨਤੀਜਿਆਂ ਦੀ ਵਰਤੋਂ ਨੂੰ ਸੀਮਤ ਨਾ ਕਰਨ ਲਈ ਸਹਿਮਤ ਹਾਂ ਬਸ਼ਰਤੇ ਅਜਿਹੀ ਵਰਤੋਂ ਕੇਵਲ ਵਿਗਿਆਨਕ ਉਦੇਸ਼(ਵਾਂ) ਲਈ ਹੋਵੇ। [ ]
- ਮੈਂ ਉਪਰੋਕਤ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਲਈ ਸਹਿਮਤ ਹਾਂ। [ ]

ਪਾਤਰ ਦੇ ਦਸਤਖਤ:

ਮਿਤੀ: _____/_____/_____

ਹਸਤਾਖਰ ਕਰਨ ਵਾਲੇ ਦਾ ਨਾਮ:

ਜਾਂਚਕਰਤਾ ਦੇ ਦਸਤਖਤ:

ਮਿਤੀ: _____/_____/_____

ਜਾਂਚਕਰਤਾ ਦਾ ਨਾਮ:

Annexure V

COLIPA SCALE

The group of experts established a set of intrinsic criteria, involving no data other than those collected on the individual case, for calculating two types of scores:

- a chronological score; and
- a semiological score.

Chronological score

The chronological score is calculated from the information on the time sequencebetween use of the cosmetic product and occurrence of the symptoms.

The time sequence between use of the cosmetic product and occurrence of thealleged undesirable effect may be:

- compatible, i.e. usual given the reported symptoms;
- only partially compatible, i.e. unusual given the reported symptoms;
- unknown;
- incompatible, whenever the clinical or paraclinical effect occurred before the cosmetic product was used or whenever the period before the observed symptoms appeared is too short.
  If the time sequence is inconsistent, the undesirable effect cannot be attributed to use of the cosmetic product.

Semiological score

The semiological score is calculated from the information on the nature of the undesirable effect and on the results of any specific additional examinations thatwere performed or of re-exposure to the cosmetic product.

a) Symptomatology

Symptomatology is defined as a set of symptoms, recorded as

exhaustively as possible during the case investigation, enabling a diagnosis to be put forward. Absence of diagnosis does not prevent use of this method.

It points to use of a cosmetic product whenever the symptoms observed are appropriate to the nature of the product or to its method of use in terms of location, effect or evolution.

It is otherwise only partially or not at all evocative.

In certain cases, factors that might have contributed to the undesirable effect, i.e. to attenuating or accentuating its clinical expression, may come to light when this information is collected. Although these factors may play a significant role, for the sake of simplification they have not been taken into account in this method.

b) Additional examinations (AE)

Any additional examinations must be reliable and specific to the observed effect and must be performed by specialist physicians.

The results of these examinations are rated as follows:

- AE (+): positive;
- AE (-): negative;
- AE (?): if no examinations were performed or if the results were ambiguous.

c) Re-exposure to the cosmetic product (R)

After the decurrence of clinical signs, there are three possibilities if the effects recur after re-exposure to the cosmetic product, whether accidental or not:

- R (+, positive): the initial symptomatology recurs with the same intensity or witha higher intensity when the user is re-exposed to the product;
- R (?): there is no re-exposure to the product or the conditions of re-exposure arenot identical to those of the initial exposure;
- R (-, negative): the effect does not recur when the user is re-exposed to theproduct.

  For re-exposure to be considered negative, it must occur under similar conditions of use of the cosmetic product (identical product, identical procedure, identical duration, etc.) without

causing an identical undesirable effect (identical symptoms and location, identical time sequence before occurrence, etc.).

These scores, combined in a decision table (Table 1) or a decision tree (Table 2), produce five levels of causality: very likely, likely, not clearly attributable, unlikely and excluded.

In this decision table, in principle causality is ‘excluded’ if the time sequence before the effect appears is considered incompatible.

When other aetiologies might account for an undesirable effect observed, these weaken the alleged link between the cosmetic product and the undesirable effect in question and, consequently, the causality is downgraded by one level, but never ‘excluded’.

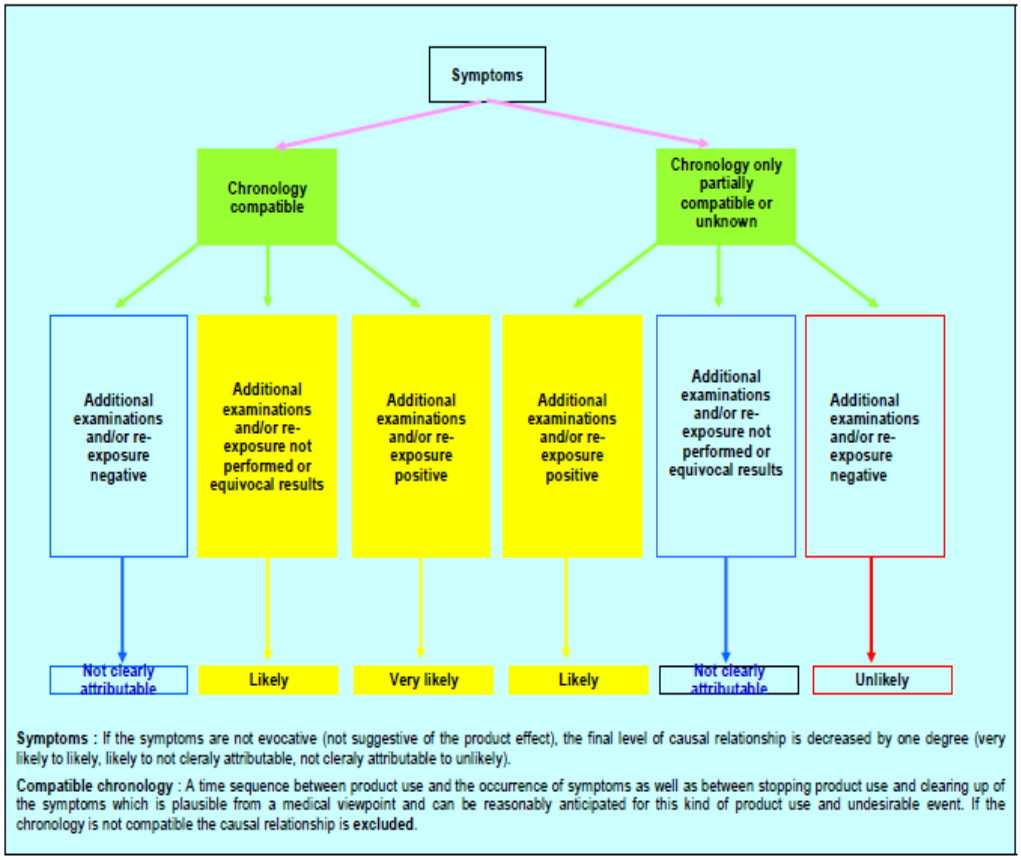
In any case where another aetiology explaining the undesirable effect observed is demonstrated, medically validated and documented, the alleged link between the relevant cosmetic product and the undesirable effect in question is excluded in this particular case. This other aetiology must be medically validated by a physician specialising in the relevant organ and, whenever possible, be reported in writing.

The excluded cases will be regularly re-assessed as scientific knowledge progresses.

Table 1: Decision table

Symptoms / Time sequence between exposure and occurrence of the symptoms	EVOCATIVE of use of the cosmetic product			ONLY PARTIALLY OR NOT EVOCATIVE of use of the cosmetic product		
	R and/or AE +	R and/or AE ?	R and/or AE -	R and/or AE +	R and/or AE ?	R and/or AE -
Compatible	Very likely	Likely	Not clearly attributable	Likely	Not clearly attributable	Unlikely
Only partially compatible or Unknown	Likely	Not clearly attributable	Unlikely	Not clearly attributable	Unlikely	Unlikely
Incompatible	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded

Table 2: Decision tree



Symptoms : If the symptoms are not evocative (not suggestive of the product effect), the final level of causal relationship is decreased by one degree (very likely to likely, likely to not cleraly attributable, not cleraly attributable to unlikely).

Compatible chronology : A time sequence between product use and the occurrence of symptoms as well as between stopping product use and clearing up of the symptoms which is plausible from a medical viewpoint and can be reasonably anticipated for this kind of product use and undesirable event. If the chronology is not compatible the causal relationship is **excluded**.

This decision table was used to establish the following definitions:

Causality VERY LIKELY	- the clinical symptoms evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is compatible; - and the specific additional examinations performed are positive and relevant(1) or the re-exposure to the product is positive(2).
Causality LIKELY	- the clinical symptoms evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is compatible; - and there are neither any relevant specific additional examinations(1) nor re-exposure(2) or otherwise the results of re-exposure or the results of the specific additional examinations performed are ambiguous. Or: - the clinical symptoms evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is only partially compatible or unknown; - and the specific additional examinations performed are positive and relevant(1) or the re-exposure to the product is positive(2). Or: - the clinical symptoms only partially evocate or do not evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is compatible; - and the specific additional examinations performed are positive and relevant(1) or the re-exposure to the product is positive(2).
Causality NOT CLEARLY ATTRIBUTABLE	- the clinical symptoms evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is compatible; - and the relevant specific additional examinations(1) or the re-exposure(2) are negative. Or: - the clinical symptoms evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is only partially compatible or unknown; - and there are neither any relevant specific additional examinations(1) nor re-exposure(2) or otherwise the results of re-exposure or the results of the specific additional examinations performed are ambiguous. Or: - the clinical symptoms only partially evocate or do not evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is compatible; - and there are neither any relevant(1) specific additional examinations nor re-exposure(2) or otherwise the results of re-exposure or the results of the specific additional examinations performed are ambiguous. Or: - the clinical symptoms only partially evocate or do not evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is only partially compatible or unknown; - and the specific additional examinations performed are positive and relevant(1) or the re-exposure to the product was positive(2).

Causality UNLIKELY	- the clinical symptoms evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is only partially compatible or unknown; - and the specific additional examinations(1) or the re-exposure(2) to the product are negative. Or: - the clinical symptoms only partially evocate or do not evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is compatible; - and the specific additional examinations(1) or the re-exposure(2) to the product are negative. Or: - the clinical symptoms only partially evocate or do not evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is only partially compatible or unknown; - and there are neither any relevant specific additional examinations(1) nor re-exposure(2) or otherwise the results of re-exposure or the results of the specific additional examinations performed are ambiguous. Or: - the clinical symptoms only partially evocate or do not evocate use of the product; - the time sequence between use of the product and occurrence of the symptoms is only partially compatible or unknown; - and the specific additional examinations(1) or the re-exposure(2) to the product are negative.
Causality EXCLUDED	- the time sequence between use of the product and appearance of the symptoms is incompatible; Or: - another aetiology was demonstrated, medically validated and documented.

(1) The additional examinations performed to objectify an undesirable effect must be specific and relevant: they must follow an established protocol and allow standardised interpretation. These specific and relevant examinations must be clearly defined.

(2) Re-exposure may occur in controlled or uncontrolled fashion. The user may either be spontaneously re-exposed to the product which caused the undesirable effect or otherwise be re-exposed to the product following a specific protocol.

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Cosmetics utilization and associated adverse events: A community based cross-sectional study

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ABSTRACT

Background: Cosmetics can enhance a person's perception of their beauty, but they can also be harmful. Despite a high incidence of adverse events, no study was conducted on cosmetics usage patterns and their associated adverse events at the community level in India.
Methodology: A cross-sectional study was conducted among the 400 general population in the Jalandhar, Amritsar, and Ludhiana regions of Punjab, India. The study was conducted from May 2021–September 2022. Data collection was done by using a validated questionnaire. Descriptive statistics were used to summarize proportions, and logistic regression was used to identify the predictors of cosmetics-related adverse events.
Results: A total of 400 respondents participated in the study. More than half of the participants (54.7%) used 1–2 cosmetics per day, with nearly fifty percent (n = 49%) reportedly using them twice daily. The most commonly used cosmetics products were makeup (35.9%), followed by personal care products (28%). A total of 132 users reported adverse events due to cosmetics. The prevalence of cosmetic-induced adverse events was found to be 33%. The most commonly reported adverse events were itching (n = 58), redness (n = 59), and pimples (n = 42). The majority of reported adverse events were related to skin care products (46%), hair care 39 (28.1%), and personal care products 24(17.3%).
Conclusion: The prevalence of adverse events among cosmetics users were found to be high. There is an urgent need to create awareness of the rational use of cosmetics among users. Additionally, the establishment of a cosmetovigilance center is also recommended.

1. Introduction

Cosmetics are any substances that are applied topically to the body in order to maintain dental hygiene, clean, perfume, protect, alter the appearance, or reduce body odour.[1] As per the US FFDCA (Federal Food, Drug and Cosmetic Act) 1938, a cosmetic is any substance used to improve or alter one's outward look.[2] Typically, they are combinations of chemical substances obtained from natural or synthetic sources. The global cosmetics market is predicted to expand considerably by 2026.[3] Cosmetics include skin care, body hair removal, antiperspirants, shaving cream, foundation, perfumes, sunscreen, hair and scalp products, and many others.[4] The use of cosmetics has grown significantly over the past several years. Cosmetics are used by both men and women however, their usage is more common among women.[5] Women may use cosmetics more frequently than men because they naturally place more emphasis on maintaining their looks, self-image, and beauty. Cosmetics usage rate is high among those who are young, highly educated, and have better economic status.[6,7]

Generally, cosmetic users are more concerned with the immediate effects of cosmetics on appearance than with the long-term effects on the entire body. These products are regarded as safe and tolerated to some extent.[8] Cosmetics can make people feel more attractive, but they can also have side effects. Numerous adverse events such as conjunctivitis, acne, photo-allergic/toxic, contact dermatitis, hypo/-hyperpigmentation, itching, corrosive scalp injury, acute hair loss, loosening of nails from the nail bed and irritation of the mucous membrane of the oral cavity were reported with cosmetics.[9–11] These effects could manifest immediately following usage or develops after repeated use. Screening and monitoring the possible side effects of cosmetics have received more attention in recent years.[12] In order to confirm the safety

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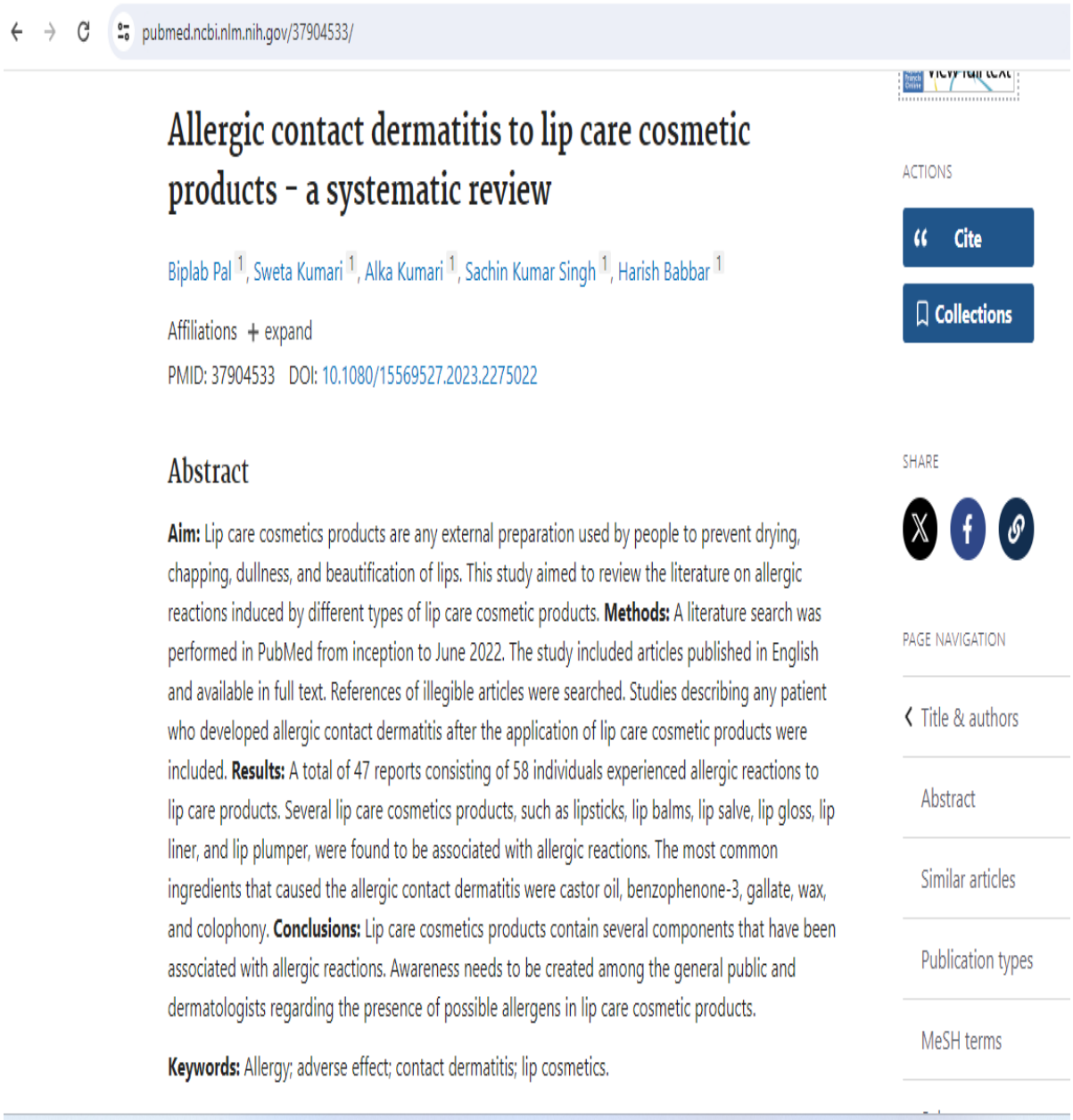
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Allergic contact dermatitis to lip care cosmetic products - a systematic review
Biplab Pal [1], Sweta Kumari [1], Alka Kumari [1], Sachin Kumar Singh [1], Harish Babbar [1]
Affiliations + expand
PMID: 37904533 DOI: 10.1080/15569527.2023.2275022
Abstract
Aim: Lip care cosmetics products are any external preparation used by people to prevent drying, chapping, dullness, and beautification of lips. This study aimed to review the literature on allergic reactions induced by different types of lip care cosmetic products. Methods: A literature search was performed in PubMed from inception to June 2022. The study included articles published in English and available in full text. References of illegible articles were searched. Studies describing any patient who developed allergic contact dermatitis after the application of lip care cosmetic products were included. Results: A total of 47 reports consisting of 58 individuals experienced allergic reactions to lip care products. Several lip care cosmetics products, such as lipsticks, lip balms, lip salve, lip gloss, lip liner, and lip plumper, were found to be associated with allergic reactions. The most common ingredients that caused the allergic contact dermatitis were castor oil, benzophenone-3, gallate, wax, and colophony. Conclusions: Lip care cosmetics products contain several components that have been associated with allergic reactions. Awareness needs to be created among the general public and dermatologists regarding the presence of possible allergens in lip care cosmetic products.
Keywords: Allergy; adverse effect; contact dermatitis; lip cosmetics.
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Prevalence and risk factors of cosmetic-induced adverse events: A systematic review and meta-analysis

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ABSTRACT

Cosmetic usage has seen a significant surge globally, driven by the desire for aesthetic enhancement. However, with this increased usage, there is a rising concern regarding adverse events associated with cosmetic products. The objective of this study was to evaluate the prevalence and risk factors of cosmetic-induced adverse events. The identification of primary studies was carried out using databases such as PubMed, Embase, Scopus, and Google Scholar. Included were studies published in English reporting the prevalence of adverse events due to various cosmetic products. Quality assessment was performed using the Joanna Briggs Institute checklist, and data extraction from primary studies utilized a standard template. Analysis was carried out using R software applying a random effects model with a 95% confidence interval. To assess determinants of cosmetic-induced adverse events, data were extracted from studies reporting adjusted odds ratios, with statistical significance observed. Out of the initially identified 1,206 unique citations, 23 articles met the inclusion criteria. The pooled prevalence of cosmetic-induced adverse events was found to be 41.1% (95% CI: 31.7; 51.1), with significant heterogeneity (I^2 = 99%; p = 0). Subgroup analysis based on region revealed the highest prevalence in Africa (53.6%), followed by South America (38.0%), Asia (35.0%), and Europe (33.4%). Students exhibited a higher prevalence (51.1%) compared to the general population (36.8%). Sensitivity analysis confirmed the stability of the pooled prevalence. Egger's test showed the presence of publication bias (p = 0.0414). The study highlighted a concerning prevalence of cosmetic-induced adverse events. The findings advocate for global cosmetovigilance, regulatory enhancements, and consumer awareness to ensure safer cosmetic usage.

INTRODUCTION

Cosmetics, designed to enhance beauty, cleanse the skin, and reduce the effects of aging [1–3], have witnessed a remarkable surge in popularity, with the industry growing by approximately 4.5% annually over the past two decades [4]. This growth can be attributed to a growing consumer demand for novel and improved products. The allure of appearing aesthetically pleasing, coupled with limited public awareness regarding the safety of cosmetic products, has led to a massive increase in their usage [5]. A diverse range of commonly utilized cosmetic products such as lipsticks, creams, lotions, nail polishes, perfumes, hair colors, eye and face makeup, deodorants, shampoos, and toothpaste contribute to this developing trend [1]. With the ever-increasing use of cosmetic products, adverse events associated with these formulations are also on the rise [6].

Despite the skin's inherent protective mechanisms, certain cosmetic ingredients possess the ability to permeate the skin barrier and induce systemic effects [7,8]. The presence of potentially harmful substances such as heavy metals, nitrosamines, phenols, hydroquinone, and steroids in cosmetic formulations highlights potential health risks for individuals [9–11]. Specifically, heavy metals, a common component in cosmetics, can cause skin irritation, damage epithelial cells, and pose risks to mucous membranes [12]. Moreover, the incorporation of preservatives, fragrances, surfactants, and dyes in cosmetic formulations aims to enhance quality and prolong shelf life [13]. However, it has been found that these substances may impart varying degrees of toxicity, ranging from mild hypersensitivity reactions to severe adverse effects

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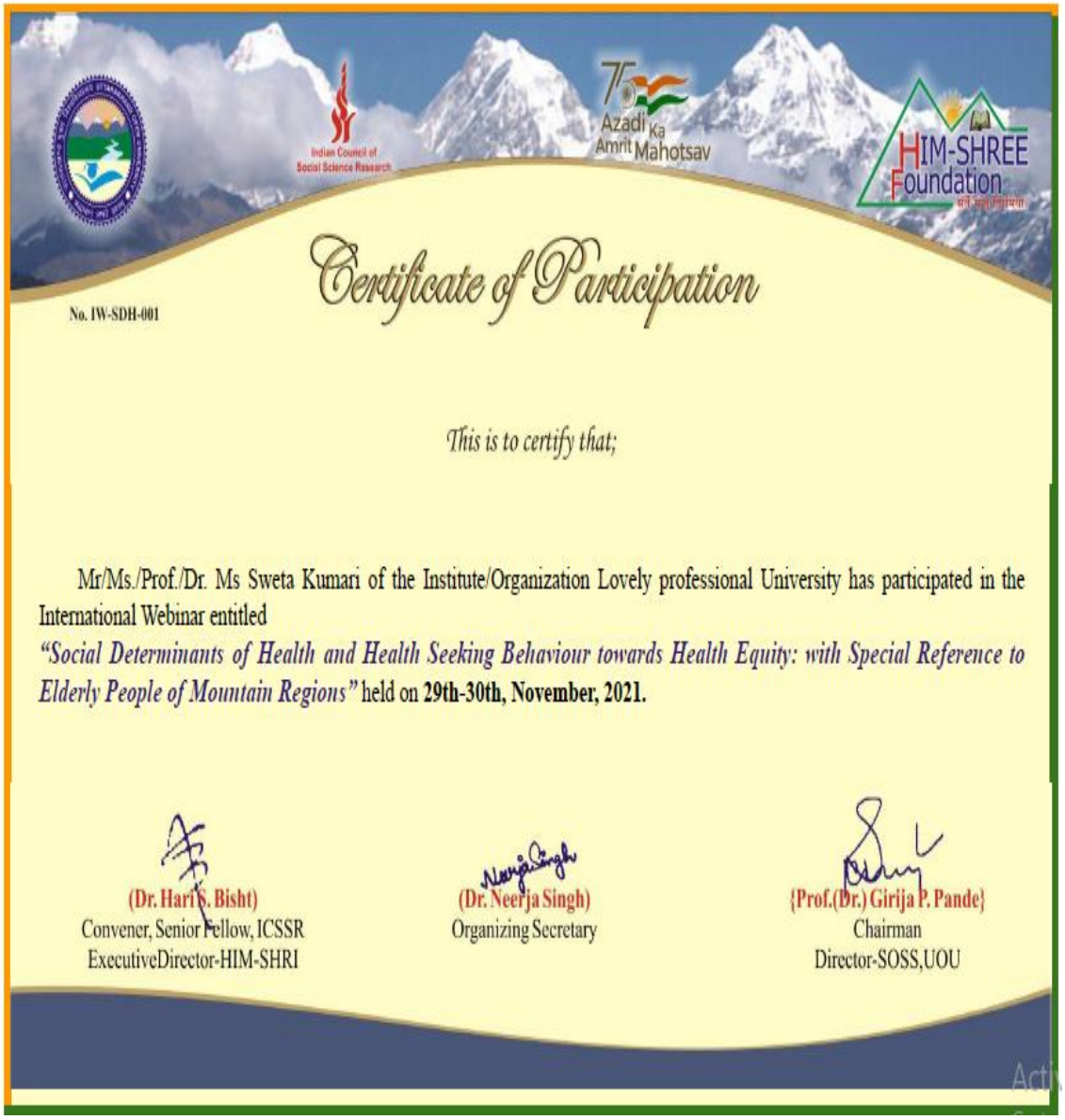
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MEDICRATES

ICSPC
International Conference on Synthetic & Pharmaceutical Chemistry

LOVELY PROFESSIONAL UNIVERSITY
Transforming Education Transforming India

NAAC GRADE A++

PHARMACY BIOMEDICAL RESEARCH INSTITUTE
Pbri
BHOPAL

Certificate of Participation

This is to certify that Prof./Dr./Mr./Ms. ***Sweta Kumari***

of ***Lovely Professional University*** *has participated in* ***Poster Presentation/Oral Presentation***

on the topic entitled ***Chemistry Behind Beauty: Unveiling the Preservatives in Eye Cosmetics and Their Role in Adverse Events***

in International Conference on Synthetic and Pharmaceutical Chemistry (ICSPC) held from 15th -16th September 2023 organized by School of Pharmaceutical Sciences, under the aegis of Lovely Professional University, Punjab.

Dr. Sanjeev Kumar Sahu
(Program Chair)

Dr. Manish Vyas
(General Chair)

Dr. Monica Gulati
(Conference Chair)

ICRAHS
INTERNATIONAL CONFERENCE ON RECENT ADVANCES IN HEALTH SCIENCES

LOVELY PROFESSIONAL UNIVERSITY
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KUST

Certificate No. 270073

Certificate of Participation

This is to certify that **Prof./Dr./Mr./Ms. Sweta Kumari** has successfully participated as **Delegate** in the **International Conference on "Recent Advances in Health Sciences" (ICRAHS-2023)** on the Theme of "Interdisciplinary Research: A key to transform Health care." from 14th April, 2023 to 15th April, 2023 organized by School of Pharmaceutical Sciences in association with Komar University of Sciences and Technology at Lovely Professional University, Punjab.

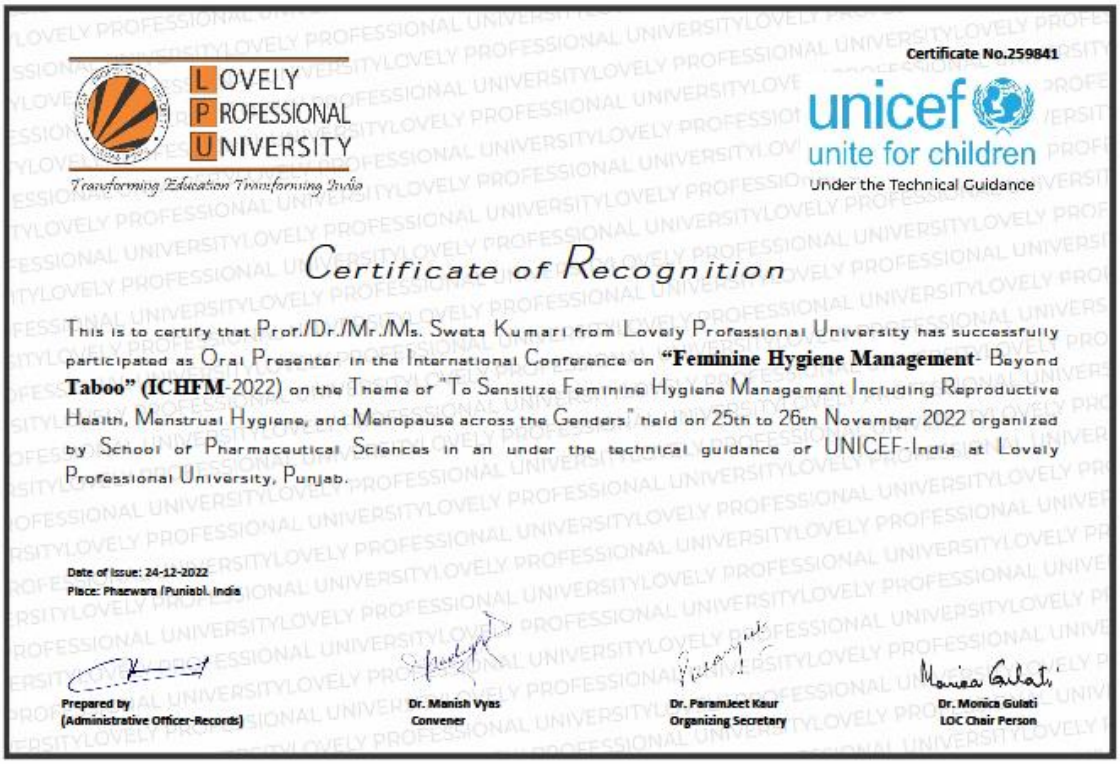
Date of Issue : 24-05-2023
Place : Phagwara (Punjab), India

Prepared by
(Administrative Officer-Records)

Dr. Navneet Khurana
Program Chair

Prof. Dr. Kawis Aziz Faraj
Conference Co-Chair

Dr. Monica Gulati
Conference Chair



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Certificate No.259841

unicef
unite for children

Under the Technical Guidance

Certificate of Recognition

This is to certify that Prof./Dr./Mr./Ms. Sweta Kumari from Lovely Professional University has successfully participated as Oral Presenter in the International Conference on **"Feminine Hygiene Management**- Beyond **Taboo" (ICHFM**-2022) on the Theme of "To Sensitize Feminine Hygiene Management Including Reproductive Health, Menstrual Hygiene, and Menopause across the Genders" held on 25th to 26th November 2022 organized by School of Pharmaceutical Sciences in an under the technical guidance of UNICEF-India at Lovely Professional University, Punjab.

Date of Issue: 24-12-2022
Place: Phagwara (Punjab), India

Prepared by
(Administrative Officer-Records)

Dr. Manish Vyas
Convener

Dr. Paramjeet Kaur
Organizing Secretary

Dr. Monica Gulati
LOC Chair Person

Serial No. 31CP2022/1517

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सत्यमेव जयते
IPC

Certificate of Participation

This is to certify that Prof./Dr./Mr./Ms. Sweta Kumari has successfully participated as Delegate & Presented Poster/ Oral Presentation on Prevalence of adverse event associated with cosmetics - A cross-sectional study in Punjab in the 3rd International Conference of Pharmacy (ICP-2022) on the Theme of "Practice, Promotion & Publication of Innovation : A Way of Transforming Health" held on 09th & 10th November 2022 organized by School of Pharmaceutical Sciences in a collaboration with Indian Pharmaceutical Association (IPA) at Lovely Professional University, Punjab.

Mr. Suresh Khanna	Dr. Bimlesh Kumar	Dr. T.V. Naryana	Dr. Monica Gulati
National Hon. Gen. Secretary, IPA	Organizing Secretary	National President IPA	LOC Chairperson

Sri Herbasia Biotech

Tishk International University, Iraq

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NAAC GRADE A++

Certificate No. 292608

Certificate of Recognition

This is to certify that **Prof .Dr./ Mr./ Mrs. Sweta Kumari** has successfully participated as a Delegate in **3rd National Pharmacovigilance Week** on the theme of "**Boosting Public Confidence in Pharmacovigilance**" held on **22nd September 2023** organized by School of Pharmaceutical Sciences, in collaboration with the Indian Pharmacopoeia Commission (IPC) Ghaziabad, IPGA Local chapter Phagwara and International Society for Pharmacoeconomics and Outcome Research (ISPOR) at Lovely Professional University, Punjab.

Date of Issue : 12-10-2023
Place : Phagwara (Punjab), India

Prepared by
(Administrative Officer-Records)

Dr. Bimlesh Kumar
Convenor

Dr. Monica Gulati
Executive Dean
Lovely Professional University