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ORIGINAL RESEARCH

Hydroquinone Levels in Unregulated Skin-Lightening Creams and Women's Knowledge, Attitudes, and Practices Toward Skin-Lightening Products in Hail, Saudi Arabia

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Background: Skin-lightening products (SLPs) are widely used in Saudi Arabia, driven by cultural ideals that associate lighter skin tones with beauty and social status. Hydroquinone (HQ), a common ingredient in skin-lightening creams (SLCs), inhibits melanin production but carries risks such as skin irritation, hyperpigmentation, and potential carcinogenicity. This study aimed to evaluate the safety of locally available SLCs and investigate consumer knowledge, attitudes, and practices (KAP) regarding SLP use in Hail, Saudi Arabia.

Methods: Ten locally available SLCs samples were collected from pharmacies and cosmetic shops in Hail. HQ concentrations were analyzed using validated UV-visible spectrophotometry, while pH levels were measured to assess their safety. A cross-sectional KAP survey of 301 residents was also conducted, exploring awareness, usage habits, and reported side effects of SLPs.

Results: Laboratory analysis showed that 80% of the samples contained HQ, with concentrations reaching as high as 7.1%. As HQ is classified as a prescription-only drug at any concentration in Saudi Arabia, the presence of HQ in unregulated products raises significant safety concerns. pH levels ranged from 2.92 to 10.04, with half of the samples outside the optimal skin pH range, posing concerns about irritation risks. Among survey participants, 63% reported using SLPs, primarily in cream form (91%). While 80% recognized potential risks, only half were aware of the ingredients in their products. Reported side effects included redness (18.75%) and pigmentation issues (15.33%), with 16.33% of users requiring medical care.

Conclusion: These findings reveal significant safety concerns surrounding locally available SLCs, with HQ concentrations frequently exceeding permissible limits and unsuitable pH levels exacerbating risks. The widespread use of SLPs despite limited consumer awareness underscores the urgent need for stronger regulations and public education to promote safer cosmetic practices in Saudi Arabia.

Keywords: cosmetics, hydroquinone, knowledge, practices, safety, skin-lightening

Introduction

The global market for skin-lightening products continues to expand significantly. The preference for a white skin tone is often seen as a symbol of social prestige and elegance globally.[1] These products include creams and ointments for skin whitening. Skin-lightening creams (SLCs), mixtures of fats and water, treat dark spots, hyperpigmentation, and age-related discoloration. Melanin determines skin color; its excess causes hyperpigmentation, melasma, and darker tones.

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The preference for lighter skin, often linked to happiness and social status, drives widespread use of these products, often without awareness of their potential harms.[2] Commonly used ingredients in these creams include mercury, arbutin, hydroquinone (HQ), kojic acid, paraben, azelaic acid, vitamin C, niacinamide, and glutathione, which can be detrimental to health.[3]

HQ, a key ingredient historically prevalent in numerous skin-lightening cream (SLC) products, functions by impeding the synthesis of melanin and limiting the production of substances that alter skin color. Historically, over the counter (OTC) SLPs in the United States contained up to 2% HQ. However, in year 2020, The United States Food and Drug Administration (US FDA) reclassified HQ as a new drug, requiring an approved application. Consequently, all OTC HQ products were removed from the market, and it is now available only by prescription.[4] Additionally, the Saudi Food and Drug Administration (SFDA) has categorized products containing HQ at any concentration as drugs.[5] Known for causing respiratory issues and skin irritation, HQ also carries potential carcinogenic effects. Owing to these health concerns, its use has been prohibited in various countries across continents including Australia, Europe, Asia, and Africa.[6]

In Saudi Arabia, the use of topical skin-lightening products is common among women, influenced by cultural beliefs that a lighter skin tone enhances marriage prospects and social standing. These societal perceptions contribute significantly to the widespread use of skin-lightening agents. The belief that fairer skin leads to improved social and professional opportunities reflects deeply ingrained cultural norms, which drive the demand and continued use of these products.[7–9]

Despite many global research on HQ levels in SLCs, data from Saudi Arabia remain limited. This study addresses that gap by evaluating HQ concentrations in locally available SLCs and the public's KAP regarding these creams. The dual focus offers a comprehensive understanding of both product composition and the societal factors influencing their application.

Materials and Methods

Quantitative Analysis of HQ in Locally Available SLCs

Samples Collection, Preparation, and Extraction

Ten locally available SLC samples were randomly purchased from pharmacies and cosmetics shops in Hail City, Saudi Arabia (Figure 1). These samples were unbranded and lacked identifiable information such as product names, manufacturers, batch numbers, production dates, or expiry dates, except for Samples 9 and 10, which used tubes from known cosmetic companies to package their locally available SLCs. The sellers claimed these products were effective for skin lightening. The samples were then transported to the laboratory for further analysis.

Figure 1 The ten samples of the locally available SLCs collected from pharmacies and cosmetic shops in Hail, Saudi Arabia, and analyzed in this study.

The study involved the quantitative analysis of HQ in locally available SLCs. An optimized ultraviolet (UV) spectroscopy method was employed for this purpose. Pure HQ was generously provided by Jamjoom Pharmaceutical Industries for use as a standard reference material. This standard underwent a rigorous validation process prior to its application in the study.

For the extraction of HQ from SLCs, a predetermined mass of each cream was dissolved in 100 mL of 96% (v/v) ethanol (Merck, Darmstadt, Germany). The samples were then incubated in a water bath at 50 °C for 20 minutes. Subsequent to incubation, the samples were agitated using a magnetic stirrer for 10 minutes and allowed to cool to room temperature prior to analysis.

Spectrophotometric Quantification Analysis

The analysis was performed using a Jenway® 6715 UV/Visible Scanning Spectrophotometer (Cole-Parmer Ltd., UK). To determine the absorption maxima (ʎ max) of HQ, a 20 ppm solution of the standard HQ was prepared and scanned in the range of 250–400 nm, with ethanol serving as the blank. The absorption peak for HQ was identified at 295 nm, and all measurements were conducted at this wavelength. For quantitative analysis, volumes ranging from 0.5 to 3 mL of the HQ stock solution (100 ppm) were diluted to a final volume of 10 mL. Method validation was conducted to ensure linearity, precision, accuracy, and to determine the limits of detection (LOD) and quantification (LOQ) for HQ in various cosmetic formulations.

Assessment of Consumer Knowledge, Attitudes, and Practices

This cross-sectional analytical study was conducted using a self-administered questionnaire, targeting the female general population of Hail City, Saudi Arabia. The study spanned two months, from October to November 2024, and was carried out across various locations, including governmental and private dermatology clinics, community pharmacies, and public areas within Hail City. Participants were required to have used SLCs and to be at least 18 years old. To ensure representation, participants from various areas of the Hail Region were randomly selected. The sample size was calculated using the Raosoft program at a 5% margin of error and a 95% confidence level, determining a minimum of 284 participants for the survey. A total of 301 participants completed the survey; however, 45 participants reported never using SLPs and were therefore excluded. The analysis focused exclusively on the remaining 256 users of SLPs. Ethical approval for this study was granted by the Research Ethics Committee at Hail University, with the registration number H-2024-505. All participants provided informed consent prior to participation, and the study was conducted in accordance with the Declaration of Helsinki. Data collection was executed through Microsoft Excel, followed by analytical processing using SPSS (Statistical Package for the Social Sciences) version 24. Descriptive statistical methods were employed to ascertain the prevalence of side effects associated with SLPs and to evaluate related KAP parameters.

Results

HQ Concentration and pH Values in SLCs

The analysis of the ten SLCs samples revealed a wide range of HQ concentrations, from undetectable levels to as high as 7.1% ±0.076. Eight of the ten samples contained detectable levels of HQ, while two samples (Creams 8 and 10) had no HQ content. Since HQ is classified as a prescription-only drug in Saudi Arabia at any concentration, its presence in unregulated products raises significant safety concerns. These findings are summarized in Table 1.

The highest HQ concentration was identified in Cream 3 (7.105% ±0.076), while Creams 8 and 10 showed no detectable HQ levels. This substantial variation in HQ concentrations, with the majority of samples exceeding safety thresholds, highlights potential health risks for consumers using these products.

The pH values of the SLCs were also assessed to evaluate their compatibility with the natural skin pH, which typically ranges from 4 to 7.[10] The pH values of the creams ranged broadly from 2.92 ±0.03 to 10.04 ±0.06, with five creams exhibiting pH values outside the ideal skin pH range. Creams 7 and 4 had the lowest pH values, 2.92 and 2.98 respectively, suggesting a more acidic formulation, which may increase skin irritation risk. Conversely, Cream 2 showed the highest pH value (10.04 ±0.06), indicating a basic formulation that could disrupt the skin barrier with extended use. The pH data are included in Table 1 alongside HQ concentrations.

Table 1 HQ Concentration and pH Values of SLCs Samples

Cream Sample	% Hydroquinone ±SD	pH Value ± SD
Cream 1	3.88 ±0.006	7.12 ±0.01
Cream 2	5.352 ±0.004	10.04 ±0.06
Cream 3	7.1 ±0.076	4.42 ±0.02
Cream 4	5.757 ±0.013	2.98 ±0.20
Cream 5	3.247 ±0.016	4.87 ±0.02
Cream 6	5.185 ±0.041	4.74 ±0.06
Cream 7	5.166 ±0.603	2.92 ±0.03
Cream 8	0.00	7.92 ±0.05
Cream 9	5.945 ±0.050	7.15 ±0.08
Cream 10	0.00	7.42 ±0.03

The organoleptic assessment evaluated the creams' color, texture, homogeneity, and odor. Most creams were opaque with smooth textures and consistent colors (off-white to green, yellow, orange, and brown), except Creams 4 and 6, which showed phase separation and color variation, indicating potential stability issues. Most creams felt light and moisturizing, though Creams 1, 2, 3, 4, and 6 had slight greasiness.

Knowledge, Attitude, and Practices

The analysis of HQ concentrations and pH levels in locally available SLCs from the Hail region revealed safety concerns. These findings prompted the incorporation of a KAP study to explore consumer behavior and awareness regarding SLC use. Demographic data from the KAP study show a predominant age range of 21–50 years (85%), indicating that SLPs usage is concentrated among younger and middle-aged adults. Most participants were married (75%) and held a university education (81%), suggesting a demographic with access to diverse beauty concepts. Additionally, 76% of participants reported having light skin color, and the median income level was Saudi Riyal (SAR) 5000 (Table 2).

Table 2 Demographic Characteristics of Study Participants

Variable	Categories	Frequency (N = 301)	%
Age	> 50	14	4.7
	15-14	1	0.3
	18-20	29	9.6
	21-30	56	18.6
	31-40	90	29.9
	41-50	111	36.9
Marital status	Single	76	25.2
	Married	225	74.8
Education	Illiterate	1	0.3
	Primary school	3	1.0
	Intermediate school	10	3.3
	Secondary school	42	14.0
	University degree	245	81.4
Occupation	Employee	164	54.5
	Housewife	52	17.3
	Student	44	14.6
	Unemployed	41	13.6

(*Continued*)

Table 2 (Continued).

Variable	Categories	Frequency (N = 301)	%
Skin color	Light	230	76.4
	Brown	69	22.9
	Black	2	0.7
Skin type*	Dry	82	28.0
	Oily	48	16.4
	Mixed	163	55.6
Monthly income**	< 5000	135	49.8
	5000-9999	57	21.0
	10000-14999	66	24.4
	15000+	13	4.8

Notes: *8 participants did not provide information. **30 participants did not provide information.

Knowledge of Participants Toward SLPs

The analysis of participants' knowledge regarding SLPs revealed varying levels of awareness (Table 3). While 80% of participants agreed that SLPs may cause unwanted side effects on the skin, 71% acknowledged the potential for systemic side effects. However, only 50% of participants knew the specific ingredients in the products they used.

The sources influencing participants' decisions to use SLPs were assessed to understand the role of social and external factors. A total of 256 participants were surveyed, excluding the 45 participants who had never used SLPs. Advertisements were the most common influence, reported by 32.8% of participants, followed by self-motivated use ("nobody") at 29.7%. Recommendations from family members (14.1%), friends (12.5%), and sisters (8.6%) were also noted, while husbands were cited the least (2.3%).

Attitudes of Participants Toward SLPs

Participants' attitudes toward skin-lightening product (SLP) use were assessed (Table 4). Environmental factors were cited by 58% of participants as a reason for using SLPs, while 22% disagreed and 20% were uncertain. When asked about addiction, 34% believed SLP use could lead to addiction, while 38% were uncertain, and 28% disagreed.

Table 3 Participants' Knowledge Regarding the Ingredients, and Potential Side Effects of SLPs (N = 301)

Question	Response n (%)		
	Agree	**Neutral**	**Disagree**
I know the ingredients of the product I am using	152 (50%)	–	149 (50%)
Skin lightening products may cause unwanted side effects on the skin	240 (80%)	40 (13%)	21 (7%)
Skin lightening products may cause unwanted side effects in the body	215 (71%)	45 (15%)	41 (14%)

Table 4 Participants' Attitudes Regarding the Use of SLPs and Their Potential Influence, Addiction Risk, and Medical Use (N = 301)

Question	Response n (%)		
	Yes	**Maybe**	**No**
Do you use skin whitening agents because of the environment you are in?*	148 (58%)	51 (20%)	57 (22%)
Can skin whitening lead to addiction?	103 (34%)	114 (38%)	84 (28%)
Do you think that skin whitening products should only be used for medical purposes?	127 (42%)	71 (24%)	103 (34%)

Note: *Those who never use skin lightening products were excluded (valid N = 256).

Regarding the medical use of SLPs, 42% agreed that such products should be reserved for medical purposes, while 34% disagreed, and 24% remained uncertain.

Practices of the Participants Using SLPs

The median age for first use of SLPs was 20 years, with creams being the most common method (91%). The median duration of SLP use was 6 years. Pharmacies were the primary source for obtaining SLPs (75%), though brand recommendations varied, with friends (35%), doctors (20%), pharmacists (15%), and others (29%) influencing choices. The main reason for SLP use was skin pigment disorders (47%), followed by personal preference (39%). Ready-made products were used by 56% of participants, while 44% relied on lightening mixtures. HQ was the most frequently mentioned SLP (8%), with 18% reporting natural mixtures. Most users (57%) reported using 2–5 products simultaneously, while 43% used only one product. Additionally, 6% used SLPs during pregnancy, 13% during breastfeeding, and 38% opted for fast whitening products (Table 5).

Reported Side Effects Following SLPs Use

The side effects reported by participants highlight the potential risks associated with SLPs use (Figure 2). While 38.28% of users reported no side effects, a considerable proportion experienced adverse outcomes (Figure 2A). Redness of the

Table 5 Participants Practices Regarding the Use of SLPs (N= 256)

Variable	Categories	Frequency (N = 256)	%
Age when first used the product* *(median = 20, IQR: 18–25)*	Baby-kid	7	2.8
	Teenager	75	29.8
	20-29	129	51.2
	30-39	40	15.9
	40-49	1	0.4
Skin lightening method	Syringe	1	0.4
	Cream	232	90.6
	Pills	5	2.0
	Soup	17	6.6
	Serum	1	0.4
Usage period** *(median = 6, IQR: 2–15)*	< 1	23	9.3
	1-2	52	21.1
	3-5	42	17.0
	6-10	1	0.4
	> 10	110	44.5
	Unstable	19	7.7
Product cost (SAR)*** *(median = 100, IQR: 50–189.75)*	< 40	41	18.6
	40-99	59	26.8
	100-199	67	30.5
	200–999	53	24.1
Source	Cosmetics store	46	18.0
	Pharmacy	194	75.8
	Supermarket	2	0.8
	The apothecary stores	14	5.5
Recommender of a certain brand	Pharmacist	39	15.2
	Friend	90	35.2
	Doctor	52	20.3
	Other	75	29.3

(*Continued*)

Table 5 (Continued).

Variable	Categories	Frequency (N = 256)	%
Reason of usage	The skin suffers from pigment disorders, for example melasma and other skin problems	120	46.9
	Light skin color is preferred	99	38.7
	None of the above	37	14.5
Product type used	Ready product	144	56.3
	Lightening mixtures	112	43.8
Product name****	Natural substances	38	17.6
	HQ	18	8.3
	More than one type	15	6.9
	Other	145	67.1
Products have you used at one time	1	109	42.6
	2–5	147	57.4
Used in pregnancy	Yes	15	5.9
	No	241	94.1
Used while breastfeeding	Yes	33	12.9
	No	223	87.1
Fast whitening	Yes	97	37.9
	No	159	62.1

Notes: *4 participants did not provide information. **9 participants did not provide information. ***36 participants did not provide information. ****40 participants did not provide information.

skin was the most commonly reported side effect (18.75%), followed by pigmentation issues (15.33%), other unspecified effects (17.58%), and acne (10.16%). These findings reflect the varying impact of SLPs on skin health, with some users experiencing more severe symptoms than others. Furthermore, the seriousness of these side effects is evident, as 16.33% of participants reported needing intensive medical treatment due to complications from SLP use (Figure 2B). In contrast,

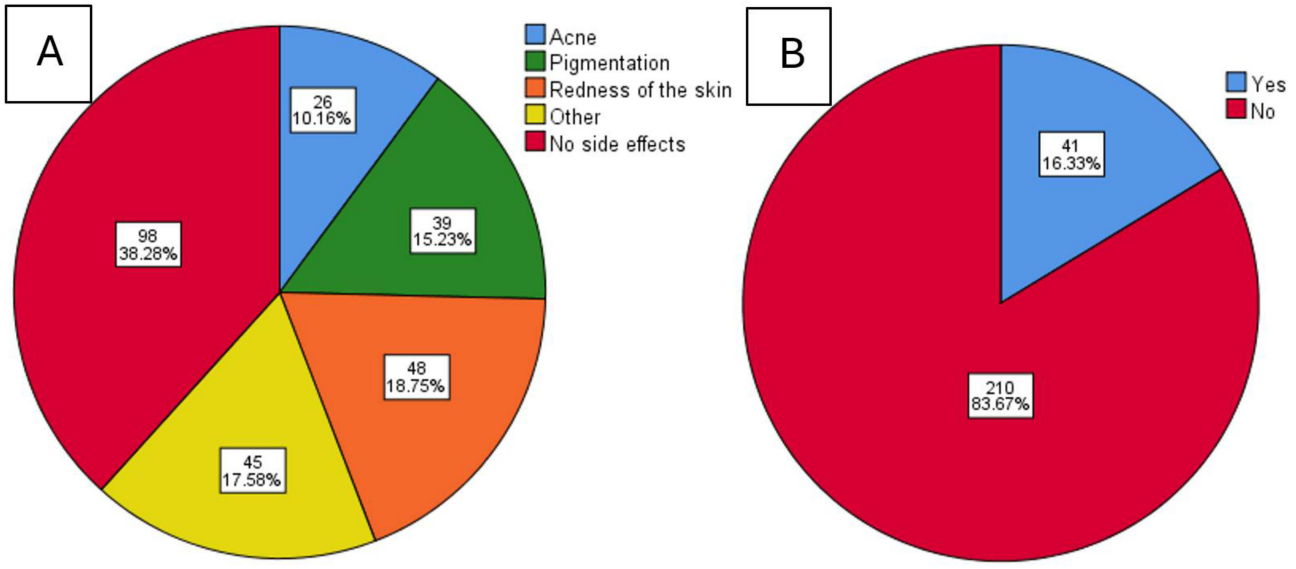

Figure 2 Reported side effects following the use of SLPs. (**A**) Types of side effects experienced by users. (**B**) Proportion of users requiring intensive medical treatment due to complications from SLPs use.

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the majority (83.67%) did not require such interventions. These results emphasize the importance of monitoring SLP use and raise concerns about the safety of unregulated products.

Discussion

The findings of this study align with international trends. In Pakistan, 11 of 22 skin-whitening products tested by thin layer chromatography and high-performance liquid chromatography methods contained HQ (0.002–0.092%).[11] Similarly, A Nigerian study using UV-visible spectrophotometry found HQ in 9 of 24 products (0.99–1.47%), including mislabeled or unlabeled items.[12] These findings emphasize significant safety concerns regarding locally available SLCs in Hail, Saudi Arabia.

Laboratory analysis showed HQ in 80% of samples, despite its reclassification as prescription-only by the US FDA and SFDA.[4,5] In the European Union, HQ is prohibited in over-the-counter cosmetic topical products and is only permitted for use in pharmaceutical formulations intended to treat hyperpigmentation.[13] One product contained 7.1% ±0.076 HQ. SLC pH values ranged from 2.92 to 10.04, with several outside the optimal skin range, risking irritation and barrier damage. The KAP analysis revealed a gap between participants' awareness of side effects and understanding of ingredients, stressing the need for public education and stronger regulation.

HQ Concentrations and pH Values in the Locally Available SLCs

The presence of HQ in unregulated SLCs, particularly the 7.105% ±0.076 found in this study, poses serious health risks, including exogenous ochronosis, systemic toxicity, and potential carcinogenicity with prolonged use.[6] These risks are heightened without medical supervision, as HQ is prescription-only under US FDA and SFDA regulations. Poor quality control in unregulated formulations leads to inconsistent HQ distribution and added risk. Similar issues were reported by Gbetoh and Amyot, who found elevated HQ levels in over half of SLPs tested across West Africa.[14]

SLCs pH values varied widely, from 2.92 ±0.03 (Cream 7) to 10.04 ±0.06 (Cream 2). Products far from the natural skin pH (4–7) can disrupt the skin barrier, causing irritation and infection risk. Highly acidic or alkaline levels compromise the stratum corneum, increasing permeability to irritants. The combination of high HQ and extreme pH in Creams 3, 7, and 2 may worsen effects such as redness, irritation, and barrier damage.[15]

KAP

Laboratory analysis of locally available SLCs revealed major safety concerns, including excessive HQ concentrations and extreme pH levels posing clear skin health risks. These findings raised questions about consumer awareness and behavior. A KAP study was conducted to explore factors driving SLPs use, knowledge of product risks, and reported side effects. Combining chemical analysis with KAP results provided a comprehensive understanding, linking product safety to user behavior and knowledge gaps contributing to health risks.

The KAP findings reveal a major gap in consumer knowledge. While 80% of participants recognized potential skin side effects and 71% acknowledged systemic risks, only 50% identified specific ingredients in their SLCs. This disconnect highlights the need to improve health literacy. A similar trend was observed in a study conducted in the United Arab Emirates (UAE), where women demonstrated awareness of the risks associated with SLPs but showed limited knowledge of their ingredients.[16] These findings emphasize the importance of targeted education and clearer product labeling to empower safer consumer choices.

The demographic data reflects the influence of societal beauty standards. SLPs use was highest among individuals aged 21–50, typically more affected by appearance pressures. This supports Hunter's findings on socio-economic and cultural factors driving cosmetic use. High education levels (81% with university degrees) and marital status (75% married) suggest that diverse beauty exposure and financial means contribute to continued SLPs use.[17]

Environmental factors were another significant motivator, with 58% of participants attributing their SLP use to perceived impacts of external conditions on skin health. This belief reflects a broader cultural perception that environmental factors, such as sun exposure and pollution, influence skin quality. Similar behaviors have been observed in East Asian populations, where individuals often stay indoors and apply skin-lightening cosmetics to achieve and maintain lighter skin tones.[18]

Another concerning finding was the difficulty in discontinuing SLP use, reported by 50% of participants. This suggests possible psychological and physiological dependency, as described by Kligman and Willis (1975), who noted rapid repigmentation from increased melanocyte activity after stopping treatment.[19] Additionally, social pressures and emotional distress linked to pigmentation differences further reinforce continued use, highlighting the complex interplay of physical and psychological reliance.

Regular use of SLPs places a financial burden on users, with a median monthly cost of SAR 150, reflecting the economic commitment to these practices. This is supported by a study conducted in Senegal, which found that the cost associated with SLPs use, compounded by expenses such as medical fees and treatment for complications, disproportionately affects individuals with low incomes, many of whom sustain these practices over an extended period.[20]

The reported side effects of SLPs use further highlight the risks of unregulated products. As shown in Figure 2A, adverse effects included skin redness (18.75%), pigmentation issues (15.33%), acne (10.16%), and other unspecified reactions (17.58%). Alarmingly, 16.33% of participants required intensive medical treatment for complications resulting from SLPs use (Figure 2B). These findings align with Olumide et al, who reported similar severe skin reactions from prolonged SLPs use.[21]

Implications of the Study

This study provides valuable insights into the use of unregulated SLPs in Hail, Saudi Arabia, and highlights important areas for action and reflection. The detection of high HQ concentrations in most tested creams, along with inappropriate pH levels, suggests opportunities for enhancing the oversight and quality control of cosmetic products. Collaboration among regulators, manufacturers, and public health bodies is vital to ensure safer preparation and sale of these products.

The findings also emphasize the importance of public education. While many participants were aware of general risks, there remains a need for more targeted awareness campaigns to inform consumers about the potential health impacts of specific ingredients in SLPs. Such initiatives could empower individuals to make safer and more informed choices. Moreover, the study reflects the societal and cultural influences that shape the demand for SLPs. Community engagement and dialogue complement regulatory and educational efforts, promoting balanced views on beauty and health.

The healthcare sector has an opportunity to contribute by counseling individuals on safe skincare practices and guiding them toward regulated and scientifically validated alternatives. Future research could build on these findings by exploring broader populations and evaluating the long-term impacts of SLPs on health and well-being.

Limitations of the Study

This study provides valuable insights into the safety and use of unregulated SLCs; however, certain limitations exist. The laboratory analysis was limited to a specific number of locally mixed products, which may not represent all unregulated SLCs available in the region. While HQ concentrations and pH levels were evaluated, other harmful ingredients were not investigated. The KAP survey relied on participants' self-reports, possibly introducing recall inaccuracies. The study also focused on women in Hail, Saudi Arabia, limiting generalizability to other populations. Despite these limitations, the study offers a crucial foundation for addressing the health risks of unregulated SLPs and improving consumer awareness.

Conclusion

This study sheds light on significant safety concerns surrounding the use of unregulated SLCs in Hail, Saudi Arabia. Laboratory analyses revealed alarmingly high HQ concentrations in 80% of the tested samples, with many products exhibiting unsuitable pH levels that could exacerbate skin irritation and other adverse effects. Despite a general awareness of potential risks, many participants lacked detailed knowledge of product ingredients, highlighting a gap in consumer education. The study highlights the urgent need for regulatory enforcement, public education campaigns, and safe, regulated alternatives to mitigate health risks posed by unregulated SLCs. Future research should aim to include diverse populations, evaluate long-term health impacts, and explore the efficacy of interventions promoting safer alternatives.

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Disclosure

The authors report no conflicts of interest in this work.

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