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Evaluating paraben concentrations in skincare products and assessing their potential health risks

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Abstract

There is a lack of specific regulations in Saudi Arabia governing the use of potentially hazardous compounds, such as parabens, in skincare products (SCPs). This study analyzed 111 feminine SCPs used in Saudi Arabia for the presence of selected parabens [namely methylparaben (MeP), ethylparaben (EtP), and propylparaben (PrP)] to assess their health risks. These parabens were highly prevalent in the examined SCPs; MeP was the most common, followed by PrP. However, we noted that ≈14% of the products were paraben-free. Nine products contained MeP, EtP, and PrP in concentrations exceeding the European Union Regulation 1223/2009 limits. The estimated daily paraben intake via dermal exposure was calculated. The combined maximum estimated daily intake (EDI) for MeP and EtP was remarkably lower than the acceptable daily intake (ADI) limit set by the European Food Safety Authority (EFSA); however, PrP levels in 23% of the products exceeded the recommended ADI limit. Although the average hazard index (HI) was below the safety threshold, 26 products had a HI > 1, indicating a potential health risk primarily due to PrP. The margin of exposure (MOE) values calculated for these parabens did not reach the safety benchmark set by the EFSA. In conclusion, MeP and EtP in the tested SCPs pose a relatively low health risk; however, the PrP content of many of these products raises concerns, especially considering the cumulative exposure to multiple parabens. This study underscores the need to monitor and regulate the use of parabens in SCPs to ensure consumer safety.

Keywords: Parabens, dermal exposure, skincare products, health risk assessment, consumer safety, estimated daily intake

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INTRODUCTION

Parabens, derivatives of para-hydroxybenzoic acid, are preferred as preservatives because of their broad antimicrobial capabilities, cost-effectiveness, nonirritating nature, and stability across various pH levels[1,2]. These compounds are widely used in personal care products, pharmaceuticals, and food owing to these advantages[3]. Parabens are classified into short-chain parabens, such as methylparaben (MeP) and ethylparaben (EtP), and long-chain parabens, such as propylparaben (PrP), isopropylparaben, butylparaben, isobutylparaben, pentylparaben, and benzylparaben[4]. This study focuses on MeP, EtP, and PrP because of their higher prevalence in consumer products and the large amount of existing safety data[2]. These compounds are widely used in consumer products because of their effective preservative properties and well-established exposure routes that are most pertinent for evaluating potential human health impacts.

Anderson[5] has highlighted the prevalent use of parabens, especially MeP and PrP, in over 22,000 cosmetic products, such as creams and lotions. Recent studies have raised questions regarding the safety of parabens as they have been linked to various health issues ranging from skin irritation to severe hormonal disruptions[6,7]. Several epidemiological studies have correlated the use of personal care products with the presence of parabens in various biological matrices, such as urine[8], follicular fluid[9], plasma[10], and hair[11].

Despite these concerns, the regulation of parabens in cosmetics varies remarkably across countries, and there is a lack of uniform standards. The European Union limits paraben concentrations to 0.4% for single compounds and 0.8% for mixtures, with recent reductions in the permitted concentrations of PrP and butylparaben[12,13]. The United States limits the concentration of multiple parabens (MeP, EtP, PrP, isopropylparaben, butylparaben, isobutylparaben, and benzylparaben) to 0.8% and that of a single paraben to 0.4%[5]. In 2020, the Expert Panel for Cosmetic Ingredient Safety reassessed the safety of 21 parabens and concluded that 20 of them are safe for use if the sum of total parabens in any given formulation does not exceed 0.8%[4].

Global personal care and cosmetics preservatives were valued at over $408 million in 2023 and heavily rely on synthetic preservatives to extend product shelf life[14]. A survey in Saudi Arabia indicated the widespread use of personal care products among women, with 16.1% of the surveyed women reporting cosmetic-related adverse events[15]. Women in Saudi Arabia spend an average of 14,256 Saudi Riyals annually on cosmetics, which is the highest in the Gulf Cooperation Council and accounts for 42% of their total expenses[16]. To address the lack of specific legislation in Saudi Arabia, this study aimed to assess the content of the most common parabens in local skincare products (SCPs), test their safety via dermal exposure, and assess the health risks linked to these compounds. Understanding safe paraben levels is essential for ensuring consumer safety and guiding manufacturers toward safer and more sustainable practices.

METHODS

Chemicals and SCPs

All chemicals used in this study were of analytical grade. The solvents, including ethyl acetate, methanol, acetone, iso-octane, and acetonitrile, were obtained from Fisher Scientific (Pittsburgh, PA, USA). The paraben compounds (i.e., MeP, EtP, and PrP) were acquired from AccuStandard (New Haven, CT, USA) in more than 97% purity.

The SCPs examined in this study were sourced from the personal collections of female staff members at the King Faisal Specialist Hospital and Research Centre. These staff members contributed a total of 111 products from renowned brands. The various product types included the following: 100 hand/body creams or body lotions, five gels, three ointments, two cleansers, and one hand balm. Except for the cleanser, these

products are categorized as leave-on and are designed for prolonged skin contact. Three products were manufactured in Saudi Arabia, while the others were imported from other countries, such as the USA, Germany, Thailand, France, Canada, and India. Six products differed in batch numbers and/or countries of manufacture despite sharing a brand name. All products were stored at room temperature (~22-25 °C) until analysis.

Sample preparation

A 7 mL solvent mix (i.e., ethyl acetate, methanol, acetone in a 2:4:4 ratio) was added to 0.05 g of each SCP sample and vortexed for 1 min. Subsequently, the samples were ultrasonicated for 30 min to facilitate the extraction of preservatives, followed by centrifugation at 3,000 rpm for 20 min at a temperature of 20 °C. The resulting supernatants were diluted with deionized water. In the purification process, C18 cartridges (500 mg, Varian Inc., USA) were preconditioned by sequentially passing solvents in the following order and volumes: first, 2 mL of iso-octane to remove hydrophobic impurities, followed by 2 mL of ethyl acetate and 2 mL of methanol to ensure the removal of less hydrophobic compounds, and finally, 2 mL of deionized water to equilibrate the cartridge for aqueous sample loading. Subsequently, preconditioned cartridges were loaded with the diluted supernatants, and the cartridges were eluted using 1 mL of 50% acetonitrile. Finally, the eluate was evaporated to dryness using nitrogen gas. Subsequently, the resultant dry residue was reconstituted in 200 μL of acetonitrile for further analysis.

Chromatographic analysis

The paraben compounds were quantified with an Alliance Waters HPLC 2,695 system equipped with a multiwavelength ultraviolet (UV) detector, Model 2,487 (Waters Corporation, MA, USA). Chromatographic separation was achieved using a Zorbax SB C18 column (12.5 mm × 4.6 mm) with a 5 μm particle size (Agilent Technologies, USA). A Waters Symmetry™ C18 guard column (4.6 cm × 2 cm; 5 μm particle size) filled with the same type of C18 silica-based packing material as the analytical column to protect it.

A Dell Optiplex GX1 computer with Millennium32 software (Waters Corporation, MA, USA) was used for data acquisition and system operation. The injection volume was 10 μL. A UV detector 2,487 with an Alliance 2,695 system from Waters was used for detection, and the excitation wavelength was set at 254 nm. The chromatography was performed using an isocratic mobile phase consisting of a mixture of acetonitrile and water in a 40:60 v/v ratio, with a flow rate of 1 mL/min. The retention times were as follows: 5.4 min for MeP, 7.8 min for EtP, and 12.3 min for PrP. The total analysis cycle time was approximately 14 min.

Validation study

Calibration curves were established by measuring paraben compounds in the SCPs for six concentrations. In the calibration phase of our analysis, six SCP aliquots were spiked with a stock solution of each paraben, resulting in concentrations of 1, 2, 4, 8, 16, and 32 μg/g wet weight. All stock and calibration solutions were prepared using acetonitrile as the solvent to ensure the consistency and reliability of paraben concentration measurement. During quantification, the peak heights of each compound were plotted against their respective concentrations using the least-squares regression method. Calibration curves derived from six individual runs exhibited a strong linear relationship. The coefficients of determination (r^2 values) were 0.9972 ± 0.0025 for MeP, 0.9985 ± 0.002 for EtP, and 0.9981 ± 0.002 for PrP, indicating excellent model fit as they explained over 99% of the variance for each compound.

The spiked samples were subjected to standard extraction and analyzed to determine recovery rates. The results indicated high analytical recovery across all tested concentrations: MeP recoveries were 96%, 94%, and 87%, with relative standard deviations (RSDs) of 15%, 8.5%, and 10.4%, respectively. EtP recoveries were

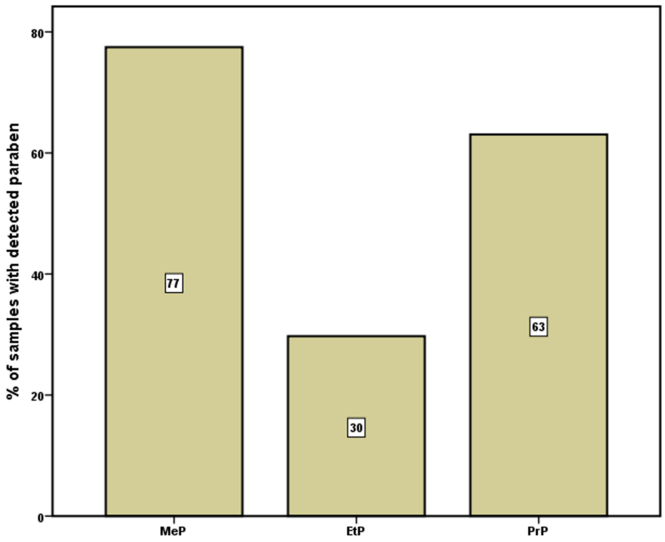

Figure 1. Bar chart showing the percentages of MeP, EtP, and PrP detected in 111 SCPs. The Y-axis represents the percentage of samples in which each type of paraben was detected, clearly indicating that MeP is the most prevalent, followed by PrP and EtP. MeP: Methylparaben; EtP: ethylparaben; PrP: propylparaben; SCPs: skincare products.

96%, 93%, and 91%, with RSDs of 10%, 6%, and 9.6%, respectively. PrP recoveries were 93%, 89%, and 108%, with RSDs of 10%, 9.9%, and 9.7%, respectively. These findings demonstrate the robustness and reliability of the extraction method at various concentration levels.

The method detection limits (MDLs) and limits of quantitation (LOQs) for each paraben were established following procedures outlined by the US Environmental Protection Agency[17]. For each compound, 10 samples were processed through the entire analytical method. The MDL was calculated using the formula: $MDL = t\ (n - 1, \alpha = 0.01) \times s$. Here, n is the number of replicate analyses; s is the standard deviation of the replicate analyses; and t is the Student's t value for $(n - 1)$ degrees of freedom at the 99% confidence level. The LOQ was determined as $LOQ = 10 \times s$. The calculated MDLs were 0.0004, 0.00043, and 0.00023 μg/g for MeP, EtP, and PrP, respectively. The corresponding LOQs were 0.004, 0.0043, and 0.0023 μg/g for MeP, EtP, and PrP, respectively. The results are reported in g/kg. The sum concentration of the three parabens was denoted as $\Sigma_3 parabens$.

RESULTS AND DISCUSSION

Frequency of parabens in SCP

In this study, 111 SCPs were analyzed to detect three common paraben compounds (MeP, EtP, and PrP). Figure 1 graphically represents the percentage of samples containing each paraben type. MeP was the predominant SCP; it was present in 77% of the samples. PrP and EtP were present in 63% and approximately 30% of the samples, respectively. Detailed information, including specific brand data, is provided in Table 1. The widespread use of MeP is reflected in Figure 1 and Table 1, demonstrating its dominance due to its broad-spectrum antimicrobial activity, stability, and cost-effectiveness. Additionally, 13.5% of the analyzed products were paraben-free, indicating a growing market trend toward "paraben-free" formulations driven by consumer concerns about potential health risks.

The preservative efficiency of parabens depends on their alkyl chain length. Longer chains imply a higher antimicrobial potency but lower solubility. Thus, products often use a mix of short- and long-chain parabens[18,19]. In our study, $\Sigma_3 parabens$ (i.e., a combination of three different parabens) were found in 86.5%

Table 1. Paraben concentrations in 111 SCPs from Saudi Arabia (g/kg)

Brand	Batch (anonymized)	Type	Source (anonymized)	Country	MeP	EtP	PrP	$\sum_3$*parabens*
Sample 1		Hand lotion	Anonymized		2.126	0.044	**1.494**	3.664
Sample 2		Body lotion	Anonymized		0.000	0.000	0.000	0.000
Sample 3	Anonymized	Body	Anonymized		2.541	0.000	0.000	2.541
Sample 4	Anonymized	Body lotion	Anonymized		1.420	0.000	1.086	2.506
Sample 5	Anonymized	Body cream	Anonymized	Thailand	2.860	0.000	**2.308**	5.168
Sample 6	Anonymized	Cream			0.887	0.000	0.437	1.324
Sample 7		Cream			2.693	0.791	0.508	3.992
Sample 8		Body lotion			0.839	0.000	0.008	0.847
Sample 9		Cream			2.235	0.000	**1.708**	3.943
Sample 10		Body lotion			2.485	0.000	0.659	3.144
Sample 11	Anonymized	Cream			2.242	0.000	**2.097**	4.339
Sample 12		Body milk			2.320	0.000	**1.840**	4.160
Sample 13	Anonymized	Hand cream	Anonymized	USA	0.000	0.000	0.000	0.000
Sample 14		Cleanser	Anonymized	Korea	**4.219**	0.000	**2.017**	6.236
Sample 15		Body lotion	Anonymized	Germany	2.903	0.000	**1.557**	4.460
Sample 16	Anonymized	Hand cream	Anonymized	Thailand	**6.686**	0.000	**2.567**	**9.253**
Sample 17		Body lotion			1.480	0.000	0.951	2.431
Sample 18	Anonymized	Body		UK	0.006	0.003	0.000	0.009
Sample 19		Cream		France	0.000	0.000	0.001	0.001
Sample 20		Cream		Germany	**6.012**	**5.033**	0.000	**11.045**
Sample 21		Cream	Anonymized	Germany	**4.344**	0.000	0.998	5.341
Sample 22		Serum			0.002	0.001	0.000	0.003
Sample 23	Anonymized	Body cream	Anonymized	USA	0.001	0.000	0.000	0.001
Sample 24	Anonymized	Cream	Anonymized	Thailand	2.077	2.972	1.121	6.171
Sample 25	Anonymized	Cream	Anonymized	France	0.000	0.000	0.000	0.000
Sample 26	Anonymized	Hand cream	Anonymized	Thailand	0.000	0.000	0.001	0.001
Sample 27		Body lotion	Anonymized	China	1.276	0.446	0.167	1.888
Sample 28		Body lotion	Anonymized		0.000	0.000	0.000	0.000
Sample 29		Hand cream	Anonymized		0.000	0.000	0.000	0.000
Sample 30		Moisturizer	Anonymized		2.752	0.005	0.963	3.720
Sample 31		Hand cream	Anonymized		0.110	0.000	0.000	0.110
Sample 32		Hair oil	Anonymized	USA	0.000	0.002	0.000	0.002
Sample 33	Anonymized	Body	Anonymized	France	0.000	0.000	0.000	0.000
Sample 34	Anonymized	Face/body/hand cream	Anonymized	UAE	0.000	0.004	0.003	0.008
Sample 35		Body lotion	Anonymized	USA	0.002	0.000	0.000	0.002
Sample 36	Anonymized	Cleanser	Anonymized		0.000	0.000	0.001	0.001
Sample 37	Anonymized	Body lotion	Anonymized	Spain	**5.051**	3.374	0.000	**8.425**
Sample 38	Anonymized	Body lotion	Anonymized	Spain	0.000	0.000	0.000	0.000
Sample 39		Body lotion	Anonymized		0.813	0.000	0.356	1.169
Sample 40		Hand cream	Anonymized	France	0.000	0.000	0.000	0.000
Sample 41	Anonymized	Hand and body lotion	Anonymized	UK	1.945	0.000	0.550	2.495
Sample 42	Anonymized	Hand and body cream	Anonymized	USA	0.361	0.000	0.034	0.395
Sample 43	Anonymized	Balm	Anonymized	Italy	0.752	0.155	1.291	2.198
Sample 44	Anonymized	Body lotion	Anonymized	UK	3.955	0.000	0.511	4.466
Sample 45	Anonymized	Body lotion	Anonymized	Croatia	1.167	0.000	0.678	1.846
Sample 46	Anonymized	Body lotion	Anonymized	USA	0.140	0.309	0.548	0.997
Sample 47	Anonymized	Ointment	Anonymized	USA	0.000	0.000	0.000	0.000

Sample 48	Anonymized	Body lotion	Anonymized	Thailand	0.873	0.233	0.137	1.243
Sample 49	Anonymized	Hand and body lotion	Anonymized	USA	0.000	0.000	0.000	0.000
Sample 50	Anonymized	Hand cream	Anonymized	Thailand	**4.365**	0.003	1.314	5.682
Sample 51	Anonymized	Hand cream	Anonymized	USA	2.432	0.000	0.805	3.237
Sample 52	Anonymized	Body lotion	Anonymized	India	2.262	0.000	0.697	2.960
Sample 53	Anonymized	Body lotion	Anonymized	USA	1.412	0.000	0.408	1.820
Sample 54	Anonymized	Body lotion	Anonymized	USA	0.881	0.000	0.233	1.114
Sample 55	Anonymized	Lotion	Anonymized	China	1.691	0.000	0.746	2.437
Sample 56	Anonymized	Body lotion	Anonymized	USA	2.115	0.033	0.732	2.880
Sample 57	Anonymized	Hand and body cream	Anonymized	USA	0.932	0.004	0.815	1.752
Sample 58	Anonymized	Lotion	Anonymized	Canada	0.970	0.245	0.485	1.700
Sample 59	Anonymized	Body lotion	Anonymized	USA	1.177	0.000	0.278	1.456
Sample 60	Anonymized	Hand cream	Anonymized	UAE	0.005	0.000	0.002	0.007
Sample 61	Anonymized	Cream	Anonymized	USA	1.477	0.108	0.260	1.845
Sample 62	Anonymized	Hand cream	Anonymized	UK	0.908	0.242	0.047	1.196
Sample 63	Anonymized	Cream	Anonymized	India	1.522	0.000	0.562	2.083
Sample 64	Anonymized	Fluid/moisturizer	Anonymized	Poland	0.003	0.000	0.002	0.005
Sample 65	Anonymized	Cream	Anonymized	Germany	0.000	0.001	0.001	0.002
Sample 66	12,267	Body lotion	Anonymized	Germany	1.129	0.229	0.090	1.448
Sample 67	CI 19140	Cream	Anonymized	UK	0.291	0.000	0.000	0.291
Sample 68	51094	Lotion	Anonymized	Australia	2.146	0.000	**1.922**	4.068
Sample 69	M6uJ6C353	Cream	Anonymized	India	0.155	0.000	**1.473**	1.628
Sample 70	5028197/255237	Body lotion	Anonymized	UK	0.002	0.001	0.000	0.003
Sample 71	30280910	Body lotion	Anonymized	USA	1.678	0.000	0.823	2.501
Sample 72	CI6096212	Hair gel	Anonymized	France	2.518	0.000	0.000	2.518
Sample 73	P52244-0	Cream	Anonymized	Canada	0.171	0.000	0.080	0.251
Sample 74	745/2	Cream	Anonymized	UK	1.283	0.365	0.231	1.878
Sample 75	20840-0-303	Moisturizer/body lotion	Anonymized	Germany	0.868	0.000	**1.888**	2.755
Sample 76	C177891	Lotion	Anonymized	Germany	2.865	0.000	**1.944**	4.809
Sample 77	128077	Cream	Anonymized	Ireland	0.000	0.003	0.000	0.003
Sample 78	115023062	Body lotion	Anonymized	Germany	2.230	0.000	**2.142**	4.372
Sample 79	VC3730	Cream	Anonymized	USA	3.734	0.000	1.376	5.110
Sample 80	83921.992.???? ?????	Cream	Anonymized	Germany	0.421	0.018	0.000	0.439
Sample 81	P51702-0	Lotion	Anonymized	Canada	0.000	0.000	0.000	0.000
Sample 82	1948592 C 0710	Nipples cream	Anonymized	USA	0.009	0.000	0.000	0.009
Sample 83	P50981-2	Lotion	Anonymized	Canada	0.000	0.000	0.000	0.000
Sample 84	30325045	Body lotion	Anonymized	USA	**4.547**	0.000	1.339	5.886
Sample 85	C10126489	Hand cream	Anonymized	USA	0.885	0.000	0.000	0.885
Sample 86	95039	Body lotion	Anonymized	UK	0.002	0.000	0.002	0.005
Sample 87	P24687-1	Gel	Anonymized	France	0.001	0.000	0.001	0.001
Sample 88	48000//736037	Ointment	Anonymized	Philippines	**11.095**	0.000	**2.666**	**13.761**
Sample 89	3574661093987	Body lotion	Anonymized	Italy	0.059	0.000	0.000	0.059
Sample 90	92225897	Cream	Anonymized	Thailand	0.022	**4.297**	**2.713**	**7.031**
Sample 91	3/060913N	Cream	Anonymized	Thailand	**14.912**	**14.151**	0.000	**29.063**
Sample 92	RGD061	Cream	Anonymized	Saudi Arabia	0.000	0.001	0.000	0.001
Sample 93	P24764-0	Gel	Anonymized	France	2.534	0.000	0.000	2.534
Sample 94	30318036	Lotion	Anonymized	USA	1.108	0.000	1.197	2.306
Sample 95	11J17/73	Cream	Anonymized	Netherlands	0.000	0.000	**3.016**	3.016
Sample 96	K2935F	Cream	Anonymized	Saudi Arab	0.000	0.131	0.000	0.131

Sample 97	Anonymized	Hand and body lotion	Anonymized	Philippines	0.816	0.000	**1.775**	2.591
Sample 98	Anonymized	Gel	Anonymized	Germany	1.218	0.000	0.000	1.218
Sample 99	Anonymized	Cream + serum	Anonymized	Canada	0.000	0.000	0.000	0.000
Sample 100	Anonymized	Cream	Anonymized	USA	0.000	0.000	0.000	0.000
Sample 101	Anonymized	Gel	Anonymized	France	0.000	0.000	0.000	0.000
Sample 102	Anonymized	Moisturizer/lotion	Anonymized	Germany	0.669	0.018	**2.181**	2.867
Sample 103	Anonymized	Lotion	Anonymized	Canada	0.000	0.000	0.000	0.000
Sample 104	Anonymized	Cream	Anonymized		0.527	1.881	0.000	2.407
Sample 105	Anonymized	Cream	Anonymized	China	0.000	0.000	0.005	0.005
Sample 106	Anonymized	Gel	Anonymized	France	0.422	0.000	0.173	0.595
Sample 107	Anonymized	Ointment	Anonymized	USA	0.000	0.000	0.000	0.000
Sample 108	Anonymized	Cream	Anonymized	Saudi Arab	0.000	0.000	0.000	0.000
Sample 109	Anonymized	Cream	Anonymized	Scotland	0.000	0.002	0.000	0.002
Sample 110	Anonymized	Cream	Anonymized	Germany	0.217	0.000	0.413	0.630
Sample 111		Petroleum jelly	Vaseline	India	0.604	0.000	**1.805**	2.409

The bold parts represent values exceeding European acceptable limits. SCPs: Skincare products; MeP: methylparaben; EtP: ethylparaben; PrP: propylparaben.

of the products, while 20.7% of the products contained only one type of paraben. The highest median concentrations were 0.813 g/kg MeP and 0.08 g/kg PrP. In general, these values were much higher than those reported by Li *et al.* (0.0475 g/kg of MeP and 0.0022 g/kg of PrP) but lower than those reported by Guo *et al.* (2.8 g/kg of MeP and 1.56 g/kg of PrP)[20,21].

The EU Regulation 1223/2009 on cosmetic products limits the total paraben concentrations in cosmetics to 8 g/kg, with no single paraben allowed to exceed 4 g/kg[13]. These limits are deemed safe for small-molecule parabens, such as MeP and EtP; however, the Safety Committee on Consumer Safety set a stricter limit of 1.4 g/kg for longer-molecule parabens, such as PrP, in cosmetics owing to concerns about their potential endocrine-disrupting effects[12]. Our study found that MeP and EtP concentrations exceeded safety limits in nine and three SCPs, respectively, with concentrations exceeding 4 g/kg. Additionally, 19 SCPs surpassed the stricter limit for PrP. Moreover, six products containing all three parabens (Σ_3*parabens*) had MeP and EtP concentrations above 8 g/kg.

Daily exposure to parabens

Parabens can be absorbed through the skin during SCP application, possibly leading to systemic absorption that increases when applied to damaged skin[22]. A recent study showed that dermal exposure to MeP, EtP, and PrP from cosmetics leads to a long half-life, with only 1.7%-2.3% excreted in the urine[23]. We calculated the estimated daily intake (EDI) of parabens via dermal contact based on the formula proposed by Guo *et al.*[21]:

$$\mathrm{EDI} = f1 \times f2 \frac{Cs \times DM}{\mathrm{BW}} \quad (1)$$

where

· $f1$ is the retention factor, which indicates the proportion of parabens remaining on the skin after application;

· $f2$ is the dermal absorption factor, which quantifies the extent to which a substance is absorbed through skin contact;

· Cs represents the concentration of parabens in the product (mg/kg);

· *DM* is the mass of the product applied to the skin (kg);
· BW is the body weight of the individual (kg).

The EDI, expressed in micrograms per kilogram of body weight per day (μg/kg-BW/day), quantifies either the intake of an individual paraben or the cumulative intake of up to three different parabens. This calculation utilizes the specific paraben concentration in SCP (*Cs*, μg/g) and the daily usage rate of these products (*DM*). For example, the daily application of body lotion is estimated at 8.69 g per day, based on data from the USEPA[24].

The retention factor ($f1$), which is the fraction of the product remaining on the skin after application, was assumed to be 1 for body and hand lotions, as per Wormuth *et al.*[25]. The dermal absorption factor ($f2$), which indicates the amount of paraben penetrating the skin, varies between 15% and 75%[26]. We used the higher end of this range (75%) in our estimates while calculating skin penetration.

We also considered the average body weight of Saudi women over 18 years old (68.8 kg), as reported by Al-Saleh *et al.*[27]. Accordingly, the mean (and maximum) EDI values for MeP, EtP, and PrP were 128.8 (1,412.6), 29.96 (1,341), and 53.97 (285.7) μg/kg-BW/day, respectively. The dermal exposure doses of MeP were more than twice those of PrP. The European Food Safety Authority (EFSA)[28] set an acceptable daily intake (ADI) limit of 0-10 mg/kg-BW/day for the sum of MeP, EtP acid esters, and their sodium salts. This limit was derived from the no-observed-adverse-effect levels (NOAELs) established at 1,000 mg/kg-BW/day for each compound. These levels are based on long-term toxicity studies and research focusing on sex hormones and their impact on male reproductive organs in juvenile rats, as reported by EFSA[28]. Notably, PrP was not included in this assessment because of insufficient NOAEL data at the time. However, the proposed ADI for PrP of 100 μg/kg BW/day was derived from a NOAEL of 100 mg/kg-BW/day[29,30].

Our study found that the maximum combined EDI for MeP and EtP (2,753 μg/kg-BW/day) was approximately four times lower than the ADI limit, even with a 75% dermal absorption rate. In contrast, the EDI of PrP in 26 (23.4%) of the products exceeded the recommended ADI, with the highest calculated EDI being approximately thrice the ADI. While our findings suggest that the presence of MeP and EtP in the tested SCP poses a low health risk, the detection of PrP in 26 products raises concerns. Honda *et al.* conducted a biomonitoring study measuring six paraben congeners in 30 urine samples collected from Saudi Arabia and calculated the EDI (μg/kg-BW/day); the values decreased in the following order: 1.3 (MeP), 0.19 (PrP), and 0.05 (EtP)[29].

Health risk assessment

Given that individuals are often exposed to multiple parabens simultaneously, the hazard quotient (HQ) was calculated for each specific paraben. The HQ reflects the ratio of the EDI to the ADI, where the ADI represents a threshold dose below which no adverse effects are expected[31]. To assess the cumulative risk from exposure to various parabens, we utilized a hazard index (HI). The HI aggregates the HQ values for three specific parabens: MeP, EtP, and PrP[32]. An HQ or HI exceeding 1 indicates that exposure levels have surpassed the acceptable dose for a single paraben or the cumulative exposure to all evaluated parabens, respectively. In our study, the HQ for PrP in 26 SCPs exceeded the safe limit, with values ranging from 1.03-2.9. The average HI for the three parabens was 0.55, indicating a generally safe level across the product range, but 26 SCPs, particularly lotions and creams, had an HI greater than 1.

The margin of exposure (MOE), a metric employed to evaluate the risk related to the presence of parabens in personal care products, was calculated as the quotient of the toxicological NOAEL value and EDI[33,34].

The formula for calculating MOE is as follows:

$$\mathrm{MOE} = \frac{NOAEL}{EDI} \quad (2)$$

where
· NOAEL: The highest exposure level at which no adverse effects are observed, typically measured in mg/kg-BW/day.
· EDI: The estimated daily intake of parabens through dermal absorption, expressed in μg/kg-BW/day.

The NOAEL values were set at 1,000 mg/kg-BW/day for MeP and EtP, and 100 mg/kg BW/day for PrP, following previous studies[28-30]. An MOE greater than 10,000 is generally considered safe, indicating a low level of health risk[33]. However, as illustrated in Table 2, none of the SCPs analyzed in this study achieved the safety threshold of an MOE exceeding 10,000. This finding suggests that even products traditionally considered safe based on dermal exposure assessments may pose potential risks if used frequently. Tokumura *et al.* reported that an MOE for PrP below the threshold signifies a high risk of disruption of the reproductive system[35]. These findings suggest that a potential health risk is associated with exposure to these specific products, primarily due to PrP, especially with frequent use. Notably, paraben exposure can also occur through other routes, such as food intake and inhalation of indoor air, medicines, and dust, which could further exacerbate the potential for health risks.

Study limitations

This study has certain limitations. First, this study focused on emulsion-based products such as creams and lotions. Hence, paraben exposure from other product types, such as gels, serums, or sprays, may not be fully captured. Future research should include a wider variety of skincare formulations to provide a more comprehensive understanding of exposure and health risks across diverse product categories. Second, the EDI for parabens was derived using hypothetical daily urinary volumes for a female subject, possibly introducing additional variability. This methodological choice, combined with the exclusion of metabolites, may affect the accuracy and reliability of our exposure assessments. This limitation underscores the need for more precise data collection and analysis methods in future studies. Third, the SCPs were exclusively collected from female staff members, limiting the generalizability of the results. Fourth, the parabens in urine samples were not analyzed. Future studies should include such analysis for a more thorough risk assessment of human exposure to parabens. Fifth, our estimates may not fully capture the actual paraben exposure levels, as the analysis was limited to the measurement of only three congeners. Finally, owing to the lack of specific dermal absorption factors for each paraben, a uniform percentage absorption rate of 75% was assumed for all parabens. Hence, the estimated EDI values may differ from the actual exposure levels.

Conclusion

In this study, 111 SCPs were analyzed. The analysis revealed a concerning prevalence of MeP, EtP, and PrP. Several products contained MeP and EtP concentrations exceeding the safety limits prescribed by the European Union. More alarmingly, an even higher number of products surpassed the stricter limits for PrP. Furthermore, our health risk assessments indicate that many of these SCPs may pose potential health risks to consumers. Given these findings, it is crucial for consumers to be informed and alert. We recommend that consumers preferentially select products that are free from parabens or those that contain safer alternatives, thereby minimizing their exposure to these potentially harmful chemicals. Retailers and manufacturers can support this shift by clearly labeling paraben contents and promoting paraben-free options. For policymakers, this study underscores the need to establish stringent, evidence-based regulatory limits on paraben concentrations in consumer products. It is advisable to tailor these limits according to local usage patterns and product types to enhance consumer safety effectively. Regulatory bodies should also

Table 2. Daily doses of parabens absorbed through the skin

	MeP	EtP	PrP	$\sum_{MeP+EtP}$	$\sum_{MeP+EtP+PrP}$
	EDI μg/kg-BW/day				
Mean	128.752	29.959	53.969	158.711	212.680
Median	77.020	0.000	7.540	82.184	125.451
Minimum	0.000	0.000	0.000	0.000	0.000
Maximum	1,412.612	1,340.554	285.701	2,753.166	2,753.166
ADI (μg/kg BW/day)	10,000	10,000	100	10,000	
> ADI	None	None	26	None	
	HQ				
Mean	0.013	0.003	0.540	0.016	0.556
Median	0.008	0.000	0.075	0.008	0.105
Minimum	0.000	0.000	0.000	0.000	0.000
Maximum	0.141	0.134	2.857	0.275	2.857
HQ > 1	None	None	26	None	26
	MOE				
Mean	27,646.938	22,896.396	154.697		
Median	91.959	975.120	1.535		
Minimum	7.079	7.460	0.350		
Maximum	492,485.713	134,110.338	2,338.780		
MOE > 10,000	15/86	12/33	None		

These parabens originate from various SCPs available in Saudi Arabia. MeP: Methylparaben; EtP: ethylparaben; PrP: propylparaben; EDI: estimated daily intake; ADI: acceptable daily intake; HQ: hazard quotient; MOE: margin of exposure; SCPs: skincare products.

consider enforcing stricter disclosure requirements to ensure transparency about the paraben content of consumer products. By adopting these recommendations, consumers and policymakers can contribute to a safer, more informed marketplace, ultimately protecting public health.

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Authors' contributions

Conceptualization, writing, formal data analysis, and supervision:Al-Saleh I
Material preparation, data collection and analysis: Al-Rouqi R
The first draft of the manuscript: Al-Qudaihi G
All authors read and approved the final manuscript.

Availability of data and materials

The datasets generated and analyzed during the current study are included in Table 1 of the manuscript.

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Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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