

# Setting the Standard of Dermal Tolerance Testing for Safe and Effective Male and Female Pubic Hair Removal

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**How to cite this paper:** Sarah, W., Aimee, P., Stephanie, C., Itziar, Z., Janice, J. and Carolyn, B. (2024) Setting the Standard of Dermal Tolerance Testing for Safe and Effective Male and Female Pubic Hair Removal. *Journal of Cosmetics, Dermatological Sciences and Applications*, 14, 343-356. <https://doi.org/10.4236/jcda.2024.144024>

**Received:** October 11, 2024

**Accepted:** December 22, 2024

**Published:** December 25, 2024

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## Abstract

Pubic hair removal has increased in frequency over recent years, with some degree of pubic hair grooming considered desirable by both men and women. Despite the increasing use of chemical depilatory creams for the removal of hair in intimate regions, there is a lack of published data regarding the safety and efficacy of such products when used for full hair removal in the genital area. This study investigated the in-use cutaneous compatibility of two thio-glycolate chemical depilatory creams for full male and female genital depilation through three single application studies. Initially, a preliminary study tested a standard male intimate chemical depilatory cream (Product A) on 18 male participants to ensure acceptable tolerance of the product. Following this, Study 1 applied Product A to 33 male participants whilst a standard female intimate chemical depilatory cream (Product B) was applied to 31 female participants in Study 2. Visual dermal assessments, together with participant-perceived assessment of tolerance, were conducted before application, and at 30 minutes, 24 and 72 hours after product removal. Study 1 reported 5 incidences (out of 33) of dermal irritation at 30 minutes post product removal, with 3 incidences remaining after 72 hours post product removal. Study 2 reported 4 incidences (out of 31) of dermal irritation at 30 minutes post product removal with 1 incidence remaining after 72 hours post product removal. Both chemical depilatory creams were concluded by a dermatologist, on the basis of dermal irritation and participant-perceived tolerance, to have achieved acceptable dermal tolerance when applied to the intended area of use for the maximum recommended application time. This data provides confidence in the safety of chemical depilatory creams when used for full removal of the pubic hair of men and women and adds to the existing published database, validating the safety and efficacy of these products for genital hair removal.

## Keywords

Dermal Tolerance, Depilatory Cream, Hair Removal, Pubic Hair, Intimate Area

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## 1. Introduction

Women's hair removal trends across the 1900s have been encouraged by changing fashions, with rising hemlines and sleeveless garments resulting in shaved legs and underarms. The first safety razor specifically for women was launched in 1915, and by 1964, 98 percent of American women were routinely shaving their legs [1]. A study examining hair removal advertisements in Harper's Bazar, found body hair removal has long been promoted for women, beginning with underarm hair in 1915 and moving to leg hair in the 1940s, with current beauty trends promoting pubic hair removal [2]. Pubic hair grooming became more common around the launch of the bikini, where hair removal was largely limited to the "bikini line", or area outside of the bikini [3] [4]. By the late 1990s, the Brazilian wax became more mainstream, offering complete removal of pubic hair [1].

Traditionally, men have not engaged in body hair depilation for aesthetic purposes, as the presence of body hair was considered masculine [5]. However over recent years, male body hair removal has appeared increasingly popular and often considered as the "norm" [6]. In recent years, there has been a steady increase in the number of depilatory products targeted at men, further indicating a change in the perception of male grooming [7].

Pubic hair removal, both partial and complete, has increased in frequency over recent years, with some degree of pubic hair grooming considered desirable by both men and women [8]. Common pubic hair removal methods include shaving, waxing and chemical depilation products. In a survey of 4585 people conducted by Enzlin *et al.* [9], 80.3% of women had current full or partial pubic hair removal, with only 3.1% reporting having never removed any pubic hair. For men, 31.9% had current full or partial pubic hair removal with 21.1% reporting never having engaged in any pubic hair removal [9]. In a further survey conducted in 2021, 64.7% of males (n = 257) and 72.8% of females (n = 471) interviewed reported pubic hair grooming, with most participants removing their pubic hair at least once a month (71.4%) [10].

Pubic hair removal has been linked to positive body image and sexual confidence, particularly among young women, however this is also increasingly the case in young men [6] [8]. Other common reasons for pubic hair removal including the desire for a "neater and cleaner" appearance, religious and hygienic reasons [10]. However, pubic hair removal is associated with potential risks; research indicates that more than 50% of young females experience at least one adverse effect due to pubic hair removal [11]-[13]. Commonly reported issues include skin abrasions, infected ingrown hairs, severe itching rashes, and other skin infections.

Chemical depilation provides the benefit of longer lasting hair removal compared with shaving, as the depilatory cream acts within the skin follicle, below where can be reached by razors [14] [15]. These products most commonly contain thioglycolate mixed with calcium, sodium or potassium hydroxide as the active ingredient. Depilatory creams function by disrupting the disulphide bonds in the hair, weakening the hair and breaking it down, allowing it to be removed from the skin. They are strongly alkaline (pH 11-13) in order to improve the efficacy and speed of breaking the disulfide bonds [16]. Depending on the active used, depilatory creams must be left on the skin for between 3 and 15 minutes to sufficiently break down the hair, before being removed [16].

Although well-established ingredients are generally regarded as safe, the high alkaline nature of depilatory creams means they have the potential to lead to skin irritation including redness, burning and itching if they are applied to the skin for longer than recommended, or used inappropriately in untested areas [17]-[19]. Whilst rare, they may also result in allergic contact dermatitis [20]. Despite the increasingly common use of depilatory products for pubic hair removal, there is a lack of published data regarding the safety and efficacy of chemical depilatory creams.

The genital area cannot be assumed to be the same as other body sites commonly targeted for hair removal, owing to differences in anatomy, proximity to mucous membranes, and exposure to external factors such as increased temperature and moisture from occlusion.

For male genital skin, the barrier function—particularly on the scrotum—is much less effective than elsewhere on the body due to the reduced stratum corneum thickness [21]. This is not an area of the body widely targeted for cosmetic product application therefore availability of tolerance data for any topical products is limited.

For vulvar skin, whilst the cutaneous epithelium of the mons pubis and labia majora exhibit a similar structure to other body sites, the semi-occlusive nature of this area means it is more hydrated than other skin [22]. This increases the potential for permeation of some topical products and increasing the susceptibility of the skin to friction effects [23].

Due to the thinner stratum corneum, proximity to mucosal membranes, and increased permeability, the genital area is at increased risk of irritation to topical products. This is a body site generally not covered by common patch testing methodology [18] and therefore requires specific dermal tolerance data to be generated in order to confirm suitability of product used for pubic hair removal.

In summary, the increased use of chemical depilatories in the genital area and the paucity of existing data drives the need to demonstrate safety and tolerability of these products in both men and women.

Therefore, the aim of this study was to explore the cutaneous tolerability of two potassium thioglycolate chemical depilatory for full hair removal in males and females.

## 2. Materials and Methods

### 2.1. Recruitment

Adult (>18 years), healthy male or female participants presenting with good skin condition, as confirmed by a dermatologist, were eligible for inclusion. Participants were eligible for inclusion if they were able to understand the study requirements and provide informed consent. Participants with any active skin conditions, a history of skin conditions or past or present medications and illness which may impact participant safety were excluded from the study.

All participants underwent a patch test on the skin of the groin to assess the acute skin reaction towards the test products in order to rule out participants who may be predisposed to an allergic irritant reaction to depilatory creams as per pack instructions and general recommendations. Only participants who did not show signs of an allergic response to the test product 24 hours after application were included in the study.

### 2.2. Ethical Considerations

Each phase of this investigation was conducted in accordance with the ethical principles of the Declaration of Helsinki, as referenced in European Union Directive 2001/20/EC, and complied with the main principles of Good Clinical Practice and all applicable regulatory requirements. Ethical approval of the study was obtained, and all participants completed written informed consent prior to proceeding.

### 2.3. Study Design

Three in-use cutaneous tolerance studies were conducted under dermatological control, to evaluate the cutaneous tolerance of two depilatory creams (Product A and Product B) used for full pubic hair removal.

### 2.4. Investigational Products

Two potassium thioglycolate depilatory creams were tested: Product A—a standard male intimate chemical depilatory cream with 10% potassium thioglycolate and a suggested maximum application time of 10 mins and Product B—a standard female intimate chemical depilatory cream with 12% potassium thioglycolate and a suggested maximum application time of 6 mins.

### 2.5. Investigational Protocol

An overview of the protocol for each study is shown in **Table 1**. A preliminary study using Product A was first conducted on a limited panel of male participants ( $n = 18$ ), in small cohorts ( $n = 5$ ) allowing acceptable tolerance to be confirmed prior to further participant exposure.

As a preliminary study with first application to this test site, acceptable tolerance (as confirmed by a dermatologist) was required before progression to the

next phases of the study (Studies 1). Studies were conducted on male and female participants, with application of Product A and B, as per **Table 1**.

**Table 1.** Study Design—Preliminary Study, Study 1 and 2.

Study	Test product	Application time	Participant sex	Test site
Preliminary study	A	Up to 10 minutes*	Male	The full genital area (not mucosal membranes)
Study 1	A	Up to 10 minutes*	Male	The full genital area (not mucosal membranes)
Study 2	B	Up to 6 Minutes*	Female	The full genital area (not mucosal membranes)

\*Product was applied to the test site for up to the stated time, with participants instructed to remove the product earlier if any symptoms of irritation occurred.

## 2.6. Depilatory Cream Application and Removal

Participants were acclimatized in standardized environmental conditions (between 18 and 24°C) for a minimum of 30 minutes. Test sites were then cleansed by the participant using a mild body wash and lukewarm water (~25°C) and blotted dry with paper towels. The test product was applied approximately 30 minutes after drying the site. Participants applied and removed the test product to and from the test sites, as per pack instructions.

## 2.7. Preliminary Study and Study 1

**Male Participants:** Product A was applied to the pubic hair on the scrotum and around the base of the penis by male participants in both the preliminary study and Study 1. Participants applied sufficient cream to ensure a consistent layer of cream 1 - 2 mm thick across the entire test site, taking care to avoid contact of the test product to the anus and perianal area, and shaft of penis.

## 2.8. Study 2: Female Participants

Product B was applied by female participants to the pubic hair across the full genital area (labia majora and mons pubis). Participants applied sufficient cream to ensure a consistent layer of cream 1 - 2 mm thick across the entire test site, taking care to avoid contact of the test product to the non-hair bearing mucosal membranes (labia minora).

Test product was left on the site for up to 10 minutes (Product A) or up to 6 minutes (Product B), with participants instructed to remove earlier if any symptoms of irritation occurred. The actual timed application of the test product on the test sites were recorded for each participant. For both depilatory creams, the product was removed by the participants themselves using a spatula or cloth, and the test site thoroughly cleaned with lukewarm water (~25°C) ensuring no residual test product remained.

## 2.9. Assessments Conducted

All assessments, including tolerance assessment, investigator assessment of tolerance, participant perceived assessment of tolerance, global assessment of tolerance and adverse events, were conducted in the Preliminary Study, Study 1 and Study 2. However, in the Preliminary Study, the assessment timepoints for all the aforementioned assessments exclude the 72 hours post product removal. The following section provides a comprehensive overview of the assessment components.

### 2.10. Tolerance Assessment

Tolerance assessments were conducted at baseline, 30 minutes, 24 and 72 hours after product removal. Assessments included grading of visual signs of irritancy by a trained investigator and self-perceived tolerance by participants. For male participants, the genital area assessed included the scrotum and base of penis, and for female participants the labia majora and mons pubis were assessed.

### 2.11. Investigator Assessment of Tolerance

The investigator evaluated the test site for visual signs of irritation, including erythema, oedema, dryness, papules and vesicles on a 5-point scale (none [score; 0], very mild [0.5], mild [1], moderate [2], or severe [3]). The Total Irritation Score (TIS) was calculated as combined score of individual visual assessments for each participant at each timepoint. Other clinical signs of irritancy (fissures, pustules, weeping, scaling) that could be linked to the nature of the product or one of its components were also subject to a clinical description and intensity graded to the same scale.

### 2.12. Participant Perceived Assessment of Tolerance

Participants assessed self-perceived dermal experience of (i) burning, (ii) stinging or (iii) other symptoms (*i.e.* feeling of dryness, itching, tension) for the test area using a 4-point scale (0 = none, 1 = slight, 2 = moderate, 3 = severe) at baseline and 30 minutes, 24 hours and 72 hours after product removal.

### 2.13. Global Assessment of Tolerance

Based on observations of dermal irritation by the investigator and consideration of participant-perceived tolerance, the study dermatologist made a global assessment of overall product tolerance per participant; Global Assessment of tolerance was provided on a five-point scale (Very Good, Good, Acceptable, Poor, Very Poor).

### 2.14. Adverse Events

Adverse events were monitored and recorded throughout the study, with the observation period beginning after the participants had signed informed consent until the last study visit for a given participant.

## 2.15. Statistics

Statistical analysis was performed for Preliminary Study, Study 1 and Study 2 separately. At each time point (baseline, 30 minutes, 24 hours, and 72 hours), irritation scores for erythema, edema, dryness, papules and vesicles were recorded as 0, 0.5, 1, 2 or 3, and Total Irritation Score (TIS) was calculated for each participant, at each timepoint, by summing these values. The percentage of participants with each score (0, 0.5, 1, 2 or 3) was presented for each parameter (erythema, edema, dryness, papules and vesicles) at each time point. For the TIS, the percentage of participants with a total score of 0, 0.5, 1, or >1 was calculated.

Changes from baseline TIS were calculated as post-baseline minus baseline at 30 minutes, 24 hours and 72 hours, and presented as mean, standard deviation (SD) and median. Tolerance was considered acceptable if the upper one-sided 95% confidence limit for the mean change from baseline TIS was less than or equal to 0.5 at all assessment times (30 minutes, 24 hours and 72 hours), as calculated using the t-distribution. If the assumptions underlying a t-distribution were violated, a confidence interval using a non-parametric method (Hodges-Lehman) was to be calculated.

## 3. Results

### 3.1. Participant Characteristics and Demographics

The number of participants who completed each study was as follows: Preliminary Study = 18, Study 1 = 33, and Study 2 = 31. The average age of participants was  $34 \pm 9.2$  years for Preliminary Study,  $39.9 \pm 9.7$  years for Study 1, and  $40.1 \pm 9.3$  years for Study 2 (Figures 1-2).

### 3.2. Preliminary Study: Preliminary Investigation of Product a Used by Male Participants

In the preliminary tolerance check of Product A, minimal dermal irritation was observed through the investigator assessment. Two instances of “very mild” (0.5) erythema were noted 30 minutes post-application with one “very mild” (0.5) erythema each on the scrotum and the base of penis.

Three reports of skin sensations were reported 24 hours after product use: one “very mild” (0.5) erythema on the scrotum and the base of penis and one “moderate” (2) erythema on the scrotum. No further signs of dermal irritation (dryness, oedema, papules, or vesicles) at any point or test site and no other clinical signs of irritancy (fissures, pustules, weeping or scaling) were noted for any participant.

Separately, the participants perceived tolerance assessment on the base of penis reported two “slight” burning sensations with one 30 minutes post product use and one 24 hours post product use. No further subjective signs of irritancy (feeling of dryness, itching, stinging or tensión) were recorded by any participant at any timepoint for this test. At the same time, five reports of skin sensation were reported by participants on the scrotum; two incidences of “slight” (1) burning 30

minutes post product use, one incidence of “slight” (1) burning 24 hours post product use, one incidence of “moderate” burning (2) 24 hours after product use and one report of a “slight” (1) feeling of tension, 30 minutes after product application. No further subjective signs of irritancy (feeling of dryness, itching or stinging) were recorded by any participant at any timepoint for this test site.

Based on these findings, the dermatologist concluded that Product A was very well tolerated by most participants, with only one participant showing poor tolerance due to a moderate burning sensation. No product-related adverse events were reported. These results indicate that Product A has an acceptable tolerance level, confirming its feasibility for progression to Study 1.

**Study 1 and Study 2: Investigation of Product A for Used by Male Participants and Product B for Used by Female Participants.**

### **3.3. Investigator Assessment of Dermal Irritation**

#### **3.3.1. Study 1**

For product A, the investigator recorded 5 incidences of dermal irritation 30 minutes after product use: four “mild” (1) and one “very mild” erythema. Four incidences were recorded 24 hours after product use: two “very slight” (0.5) erythema, one “mild” (1) erythema and one “very mild” (0.5) papules. Three instances of papules remained 72 hours post product use: two “very mild” (0.5) and one “mild” (1). No incidence of oedema, dryness or vesicles were reported any at timepoint for Product A. No further clinical signs of irritancy (fissures, pustules, weeping, scaling) were noted for any participant.

#### **3.3.2. Study 2**

For product B, the investigator recorded four incidences of dermal irritation 30 minutes after product use: three “very mild” (0.5) erythema and one “very mild” (0.5) papules. Three incidences were recorded 24 hours after product use: one “very mild” (0.5) erythema, one “very mild” (0.5) dryness and one “very mild” (0.5) papules. One instance of “very mild” (0.5) papules remained 72 hours post product use. No incidence of oedema, dryness or vesicles were reported any at timepoint for Product B. No further clinical signs of irritancy (fissures, pustules, weeping, scaling) were noted for any participant.

### **3.4. Participant-Perceived Tolerance Assessment**

#### **3.4.1. Study 1**

Nine reports of “slight” skin sensations were recorded 30 minutes after use of Product A, reducing to two incidences at 24 hours. No skin sensations were recorded at 72 hours (**Figure 2**, Panel B).

#### **3.4.2. Study 2**

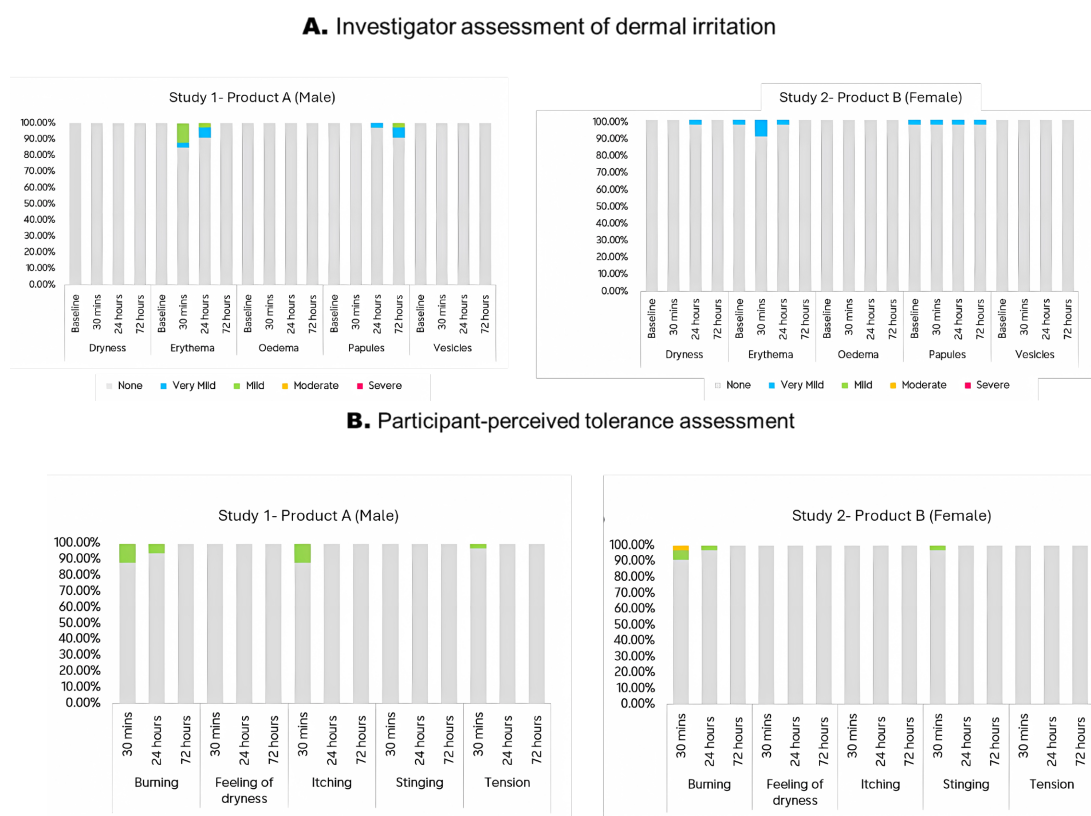
For Product B, three “slight” (1) and one “moderate” (2) skin sensations were reported 30 minutes after product use, one “slight” (1) sensation was reported at 24 hours, and no skin sensations were recorded at 72 hours (**Figure 2**, Panel B).

### 3.5. Overall Global Assessment of Tolerance

On the basis of the investigator assessment of dermal irritation and participant perceived tolerance, the dermatologist concluded Product A to be very well tolerated by most male participants and Product B to be very well tolerated by all female participants.

### 3.6. Adverse Events

No product related adverse events were reported for Product A and Product B (Figure 1).



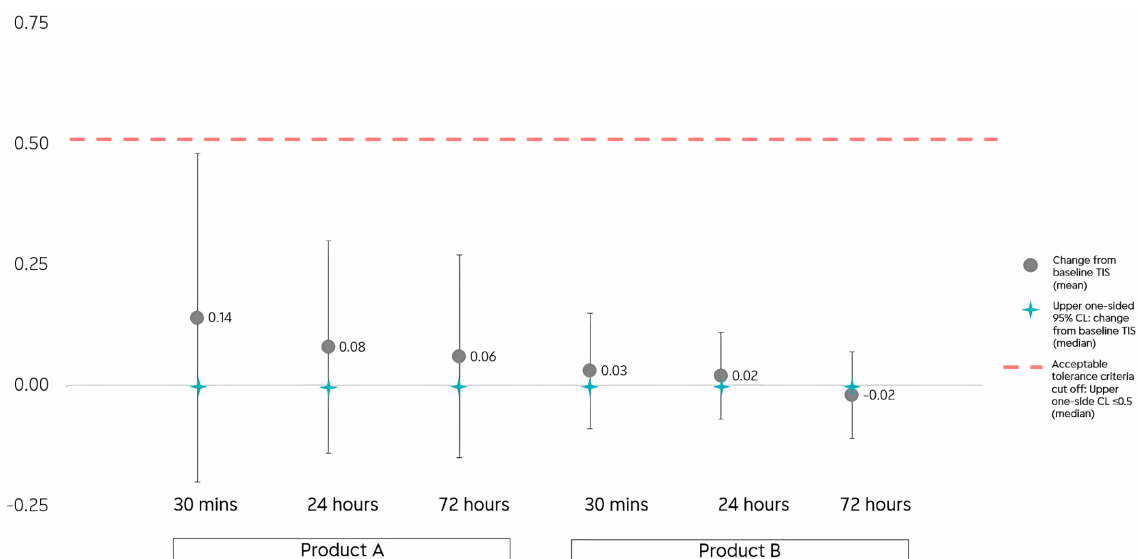
Panel A: Investigator assessment of dermal irritation. Panel B: Participant-perceived tolerance assessment (% = percentage of participants with reported signs for each score).

**Figure 1.** Results of Product A and Product B.

#### Studies 1 and 2: Total Irritation Score (TIS)

The change from baseline in total irritation score at 30 minutes, 24 hours and 72 hours was (0.14) (SD = 0.34), (0.08) (SD = 0.22) and (0.06) (SD = 0.21) for Product A and (0.03) (SD = 0.12), (0.02) (SD = 0.09) and (-0.02) (SD = 0.09) for Product B formulation (Figure 2). As the majority of Study 1 and Study 2 participants had a TIS score of zero at each timepoint (Table 2), the distribution of the data was non-parametric and therefore a confidence interval using a non-parametric method (Hodges-Lehman) was calculated. The upper 95% confidence limit for

each test product remained within the success criteria for acceptable tolerance at all timepoints for all products (95% CI = 0.00 in all cases) (Figure 2).



Mean, Standard Deviation (SD), upper one-sided 95% confidence limit (based on the median change from baseline in TIS). The cut off for acceptable tolerance is shown in red—the upper one-sided 95% confidence limit (based on the median change from baseline in TIS)  $\leq 0.5$ .

Figure 2. Change From Baseline Total Irritation Score (TIS) For Product A and Product B.

Table 2. Total Irritation Score (TIS): Percentage of Participants with a Score of 0, 0.5, 1 or Greater Than 1.

		Total Irritation Score (TIS)			
		0	0.5	1	Count >1
Product a (study 1)	Baseline	100.00%	-	-	-
	30 minutes	84.80%	3.00%	12.10%	-
	24 hours	87.90%	9.10%	3.00%	-
	72 hours	90.90%	6.10%	3.00%	-
Product b (study 2)	Baseline	93.55%	6.45%	-	-
	30 minutes	87.10%	12.90%	-	-
	24 hours	93.55%	3.23%	3.23%	-
	72 hours	96.77%	3.23%	-	-

#### 4. Discussion

The use of depilatory creams for the removal of pubic hair is increasingly common among men and women. Despite this increase, few studies report on the safety/ tolerability of these creams for use in this region. Further, the genitals of both men and women present unique challenges in ensuring product suitability in this area, driven by their distinct skin structures and proximity to mucosal membranes. Whilst chemical depilatory creams can offer benefits over razors in the removal

of pubic hair, their high alkaline nature may lead to skin irritation when used inappropriately or on unsuitable body areas. Therefore, this study has demonstrated acceptable tolerance for application of two depilatory creams for use on male and female genital skin during a series of clinical tolerance studies.

#### **4.1. Preliminary Study: Key Findings**

Due to the thinner skin and high prevalence of sensitivity to topical irritants in the genital area, a preliminary study was first conducted on a smaller cohort of male participants to gather baseline data on the tolerance of a chemical depilatory cream on the male intimate area. The acceptable tolerance demonstrated by Product A in this study provided confidence in the suitability of its use on the male genital area for pubic hair removal and provided sufficient confidence in the suitability of Product A for further investigation of a larger cohort of male participants.

#### **4.2. Studies 1 and 2: Key Findings**

Both potassium thioglycolate chemical depilatory creams, Products A and B, achieved acceptable dermal tolerance when applied to male and female genital areas for the maximum recommended application time, as assessed by both the investigator and the participants.

These results provide confidence in the tolerability of two depilatory creams for use for male or female pubic hair removal and provide data to support the use of such products in previously untested body areas.

#### **4.3. Consideration of Testing for Male and Female Intimate Skin**

Whilst acceptable tolerance was achieved for these thioglycolate creams when applied on the full genital area of male and female participants, male participants showed increased sensitivity on the intimate area versus women, as shown by the higher change in mean TIS from baseline when compared with female participants. This is likely driven by the difference in skin type between the test sites, with the scrotum presenting with thinner skin than the labia majora. As the male hair removal trend is on the increase, this highlights the need for clinical tolerance evidence strategies to better represent biologically male and female consumers.

#### **4.4. Visual Irritation Versus Perceived Irritation**

The methodology covered both subjective perceptive and objective visual assessment of tolerance by a trained investigator, as little correlation is known to exist between an individual's perception of the sensitivity of their skin and demonstrable signs of skin irritation [19] [23]. By including both methodologies, we ensured that both the visual sign and perceived sensations of irritation were fully captured during this evaluation of product suitability for the target consumer and body site.

#### 4.5. Future Considerations

As the demand for pubic hair grooming continues to grow across both sexes, the need for the development of depilatory products suitable for use in this area also increases. These studies demonstrate that it is possible to achieve acceptable dermal tolerance of depilatory products in the intimate area, against both visual signs of irritation and subjective irritation.

It is important to continually monitor how products are being used on market in order to adapt tolerance test methods to prove products remain suitable. Future considerations should include assessment of depilatory products with different formats, active ingredients, application times, and expected consumer use occasions. Furthermore, the clarity of usage instructions is an important factor, and consumer compliance should be monitored and considered in future product developments and labelling

#### 4.6. Limitations

We have shown acceptable tolerance of the products tested when used within the instructed time limit and on the designated areas, however consumer usage does not always reflect on pack instructions. We therefore make no conclusions about the dermal tolerance of the products when applied for longer than the tested duration or to intimate mucosal membranes.

In regard to the small number of study participants, while it may not fully represent the broader population, however, the findings provide valuable insights and help fill gaps in existing data on the safety and efficacy of chemical depilatory creams for genital hair removal and serves as a foundation for future, larger-scale studies.

As a form of disclosure, this study was conducted by the manufacturer of the mentioned products. However, the study was conducted with all relevant test guidelines and the purpose was to provide insight on the safety and efficacy of chemical depilatory products to provide transparency on the product itself. All forms of data disclosed here were true to the report.

#### 5. Conclusion

The two potassium thioglycolate chemical depilatory creams evaluated during this study achieved acceptable dermal tolerance when applied to the intended area of use for the on-pack maximum recommended application time, as assessed by both the investigator and the participants. Our data provides confidence in the safety of these products when used for the full removal of the pubic hair of men and women, according to usage instructions. In a field where this data is not routinely made publicly available, our data demonstrates the importance of clinical testing that reflects the increasing prevalence of pubic hair removal, together with emerging consumer trends of the usage of depilation products. Moving forward, this tolerance test methodology for hair removal on intimate areas will be part of Reckitt's routine methodology for our depilatory clinical studies.

## Acknowledgments

We would like to thank Tom Smith and Simon Lee for providing safety review of the test products and methodology presented.

## Conflicts of Interest

Authors are employees of the company who sponsored the study and manufacture the products investigated. The authors declare no conflict of interest.

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