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Association between hair-styling pomades and ocular adverse events in Brazilian cosmetovigilance data

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Abstract

Objective: To assess whether notifications involving hair-styling pomades were associated with ocular adverse events versus other cosmetics in Brazilian cosmetovigilance data.

Methods: We conducted a retrospective observational study of cosmetic adverse-event notifications from 2007 through 2025 in three Brazilian reporting systems (NOTIVISA, e-Notivisa, and LimeSurvey). Unique notifications with recorded sex, age group, and cosmetic product were included. Ocular adverse events were defined as MedDRA eye-disorder terms in coded or free-text fields. Logistic regression estimated reporting odds ratios adjusted for notification year, region, sex, age group, and self-reported race/skin color. AI-assisted tools were used only for language editing and formatting.

Results: Among 3,705 eligible notifications, 686 involved hair-styling pomades and 3,019 other cosmetics. Ocular adverse events were identified in 584 pomade-related notifications and 130 notifications involving other cosmetics (85.1% versus 4.3%). The association persisted after adjustment (adjusted reporting odds ratio: 52.46; 95% confidence interval: 29.18-94.33). Keratitis was the most frequent ocular term among pomade-related notifications.

Discussion: Hair-styling pomades were disproportionately associated with ocular adverse events in Brazilian cosmetovigilance data, with most pomade notifications concentrated in 2023. These findings represent a surveillance signal rather than an estimate of incidence or absolute risk and warrant investigation of formulations, stronger postmarketing monitoring, and clinical confirmation.

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Keywords

cosmetovigilance; cosmetics; hair-styling pomades; ocular adverse events; public health surveillance

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Introduction

Cosmetics are used worldwide for hygiene, appearance, and personal care, but adverse events can occur. Cosmetovigilance provides a public health framework for collecting, assessing, and using information on undesirable effects associated with cosmetic products.[1,2] In Brazil, the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, Anvisa) establishes health requirements for the classification, registration, labeling, and control of personal hygiene products, cosmetics, and perfumes.[3]

Hair-styling pomades are cosmetics applied near the face and intended to style, hold, or finish hair. In Brazil, products intended to fix or style hair became subject to specific temporary conditions for regularization, commercialization, and use under RDC 814/2023.[4] Eye contact may occur during application, hand-to-eye transfer, washing, runoff, or accidental exposure. Studies of eye cosmetics show that cosmetic products may migrate to the tear film, supporting ocular exposure as a plausible concern for products used near the face.[5]

Reporting databases can identify clusters of records, recurring products, and patterns compatible with a suspected outcome. Their interpretation, however, depends on the reporting context, product-use patterns, and quality of the available information. For hair-styling pomades, national cosmetovigilance data provide an opportunity to examine whether ocular adverse events are concentrated in notifications involving this product group.

In this context, this study compared adverse-event notifications involving hair-styling pomades with notifications involving other cosmetics to evaluate their association with ocular adverse events in Brazilian cosmetovigilance data, accounting for sociodemographic, temporal, and regional characteristics relevant to public health surveillance.

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Materials and Methods

Study design

This was a retrospective disproportionality analysis of spontaneous adverse-event reports from three Brazilian cosmetovigilance systems, using routinely collected data. Notifications were classified by whether they contained an ocular adverse event, and the reporting odds of this event were compared between notifications involving hair-styling pomades and those involving other cosmetics. The study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement and, where applicable, its extensions for routinely collected health data (RECORD) and for pharmacoepidemiology (RECORD-PE).[6-8]

Setting and data sources

The analysis used cosmetic adverse-event notifications from three reporting sources. The Health Surveillance Notification System (Sistema de Notificação em Vigilância Sanitária, NOTIVISA) is Anvisa's official platform for reports from companies and health professionals about adverse events and technical complaints related to products and services subject to health surveillance. LimeSurvey and e-Notivisa served as tools for receiving spontaneous reports from members of the public and consumers about occurrences and technical complaints involving regulated items, including cosmetics, personal hygiene products, sanitizing products, and foods.[9,10] Notifications were recorded from 2007 through 2025, and the data were extracted in February 2026; 2025 was therefore treated as a complete year. Anvisa provided the three databases through an institutional extraction. All three sources generate spontaneous reports, which record what the notifier described and have no exposure denominator; the authors did not verify the reports or assess causality.

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Data processing and deduplication

The three databases were consolidated and processed in Python 3.12.12, which standardized text, checked case identifiers, and standardized municipality names to the official names of the Brazilian Institute of Geography and Statistics (IBGE); names without a safe match were treated as missing. Product categories, events, and the ocular outcome were derived in this study from the report fields, as described below, rather than taken from the source databases. No person-level or institutional linkage with external datasets was performed, and all analyses used fields available in the three notification sources.

Duplicate records were identified from the case identifier and, across sources, by matching date, recorded sex, age in completed years, municipality, and specific product. Only exact matches were excluded: when exactly one record per source matched and the reported events were compatible (at least one event class in common, or no event informed in one of the records), the record from the source with the highest priority was kept (NOTIVISA, then e-Notivisa, then LimeSurvey).

Participants

The notification was the analytical unit. Eligibility criteria were applied sequentially to the consolidated records of the three sources: (1) exclusion of duplicate records, identified as described above; (2) exclusion of records without recorded sex or age group, including those with implausible ages (see Other variables); and (3) exclusion of records whose reported product was not classified as a cosmetic. The eligible sample thus comprised unique cosmetic adverse-event notifications with recorded sex, age group, and cosmetic product.

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Exposure

The exposure was the reported product category: hair-styling pomades or other cosmetics. The reported product was first assessed for whether it fell within the regulatory scope of cosmetics in Brazil,[3] and eligible notifications were then classified as hair-styling pomades or other cosmetics. Products were classified from curated lists of names, descriptions, and brands organized by the Brazilian regulatory categories of cosmetics. The lists were refined iteratively: unclassified product texts were reviewed and conservative triggers (names, descriptions, and brands) were added, and matching ignored case and accents. Hair-styling pomades were defined as products intended to style, hold, or finish hair, regardless of trade name, including pomades, styling pastes, waxes, and equivalent hair-styling products. A notification involving a hair-styling pomade together with another product was classified as hair-styling pomades. All remaining cosmetic notifications formed the comparison group, as is usual in disproportionality analyses, in which the reporting of an event for one product is compared with its reporting for the other products in the same database.[11,12] The report fields did not support further classification by brand, formulation, ingredient, batch, application setting, or professional versus home use.

Outcome

The outcome was the presence of an ocular adverse event in the notification, defined as at least one reported event classified in the Eye disorders System Organ Class (SOC) of the Medical Dictionary for Regulatory Activities (MedDRA, Portuguese version 28.1; Afecções oculares),[13] according to the rules described below. For the binary outcome, each notification was counted once, even when it contained several ocular terms; for the description of events, all ocular terms were retained, so a single notification could contribute more than one term.

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Reported events were classified separately in each report field (coded terms, checked symptoms, and free-text descriptions). Coded and checked fields were classified by mapping ICD-10 codes to SOCs, by curated lists of trigger phrases (one list per SOC), and by matching to preferred and lowest-level terms. In free-text fields, an event was classified as ocular when the same sentence contained an ocular diagnosis or finding (for example, keratitis), or an anatomical anchor (eye, ocular, cornea, eyelid) together with a symptom (for example, irritation or pain), excluding negations and label instructions. Text that matched no rule was kept as unclassified.

Other variables

Additional variables were notification year, Brazilian macro-region, recorded sex, age group, self-reported race/skin color, and seriousness. Race/skin color was taken from the self-reported field of the reports and treated as a social classification, not a biological attribute; Preta and Parda were grouped as Black or Pardo (Pardo is a Brazilian category commonly used for brown or mixed race/skin color), and White, Asian (amarela), Indigenous, and missing or unknown were kept as separate categories. Age was calculated in completed years, and recorded ages above 110 years were considered registration errors and treated as missing. Age was grouped as 0-11 (children), 12-17 (adolescents), 18-44, 45-59, and 60 years or older. Seriousness, used only descriptively, was derived from source-specific fields and classified as serious when the record indicated death, permanent injury, hospitalization or continued hospitalization, a medical visit, or care at a health service; all other records were classified as not serious.

Bias and study size

To limit the biases inherent in spontaneous reporting, the three sources were consolidated, duplicate reports across sources were excluded, products and events were classified by the same rules in every source, and the comparison group came from the same databases and reporting

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channels as the exposed group. Notification year, region, recorded sex, age group, and self-reported race/skin color were included in the adjusted model to account for differences in reporting patterns. All eligible notifications from the three sources were analyzed, and no sample size calculation was performed.

Statistical analysis

Notifications and ocular adverse events were described by absolute and relative frequencies according to notification year, Brazilian macro-region, recorded sex, age group, self-reported race/skin color, seriousness, and product category, with missing or unknown values kept as a separate category. The proportion of notifications with an ocular adverse event was compared across the categories of each variable using Pearson's chi-square test or Fisher's exact test when any expected cell count was below 5.

Crude and adjusted logistic regression models estimated reporting odds ratios (RORs), the odds of a notification containing an ocular adverse event in one category relative to the reference category, with 95% confidence intervals (CIs). The adjusted model included notification year, region, recorded sex, age group, self-reported race/skin color, and product category. Seriousness was not included because it incorporates consequences of the event and is not an antecedent confounder of the association between product category and the outcome. Regression analyses were restricted to complete cases: records with inconsistent values in model variables or with missing or unknown race/skin color, and category levels with nine or fewer notifications containing an ocular adverse event, were excluded. The reference category was the most frequent category of each variable (White for race/skin color). In models with complete or quasi-complete separation, convergence failure, or unstable estimates, Firth's penalized likelihood logistic regression was used.[14,15] Model adequacy was assessed by checking for separation,

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multicollinearity (generalized variance inflation factors), influential observations (Cook's distance), and calibration (Hosmer-Lemeshow test).

To estimate the probability of an ocular adverse event by age, the adjusted model was refitted with age in completed years as a natural cubic spline (interior knots at 8, 14, 20, and 40 years) instead of age groups. The knots were chosen by the lowest Akaike information criterion among candidate specifications, a data-driven choice. For each age from 0 to 80 years and each product category, the predicted probability was averaged over the observed distribution of the other covariates in the model sample, and the 95% confidence interval came from 600 simulations of the coefficients.

Among the notifications with an ocular adverse event, ocular terms were counted one by one, so a single notification could contribute more than one term; those with no specific term were listed as other ocular event. Terms were grouped into four clinical categories (corneal and conjunctival injury or inflammation, irritative symptoms and signs, visual disturbances, and nonspecific terms) and ordered within each by frequency for hair-styling pomades.

Analyses used R software, version 4.5.3, with the arrow, dplyr, ggplot2, knitr, stringr, and logistf packages. Statistical significance was defined as $p < 0.05$.

AI-assisted tools (OpenAI Codex CLI and Claude) were used only for English-language editing, formatting, and manuscript-structure refinement, not for data analysis or interpretation; see the Declaration of Use of Artificial Intelligence (AI).

Ethics

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Research Ethics Committee of Hospital Daher (protocol no. 77435024.4.0000.0257; approval

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opinion no. 6,692,486, dated March 8, 2024). Individual informed consent was waived because the study used secondary data from adverse-event reporting systems and involved no contact with participants or intervention. The analysis used only the fields required for the study objectives, and results are presented in aggregate form, which protects the identity of reporters, affected individuals, professionals, establishments, and products.

Results

Figure 1 presents the selection flowchart. Of the 4,421 records consolidated from the three reporting sources, 13 duplicates were excluded, and 3,705 notifications met the eligibility criteria: 686 involving hair-styling pomades and 3,019 involving other cosmetics. Ocular adverse events were present in 714 of these notifications.

Table 1 summarizes notification characteristics and the distribution of ocular adverse events across categories. The proportion of notifications with an ocular adverse event was higher for hair-styling pomades (85.1%) than for other cosmetics (4.3%), and higher in 2023 (74%) than in 2025 (2%). The proportion differed across the categories of every descriptive variable in unadjusted tests ($p < 0.001$).

Table 2 presents crude and adjusted RORs for ocular adverse events. The adjusted model included 2,479 of the 3,705 notifications. Notifications involving hair-styling pomades had higher reporting odds of an ocular adverse event than notifications involving other cosmetics (adjusted reporting odds ratio: 52.46; 95% confidence interval: 29.18-94.33; crude: 127.24; 96.74-167.36). These checks showed no separation, variance inflation factors below 2.5, no influential observations (maximum Cook's distance 0.02), and no evidence of poor calibration (Hosmer-Lemeshow $p = 0.09$). Recorded sex and self-reported race/skin color were not

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associated with the outcome after adjustment, although the crude association for Black or Pardo individuals was strong. Adjusted reporting odds were higher in 2007-2024 than in 2025, and higher at 12-17 years than at 18-44 years.

Figure 2 shows higher modeled probabilities of ocular adverse events for hair-styling pomades than for other cosmetics at every age. For both product groups, probabilities peaked in adolescence (73.1% at 15 years for hair-styling pomades; 9.4% for other cosmetics), and for hair-styling pomades they were lowest in childhood. Estimates became imprecise above 70 years, when few notifications were available.

Table 3 groups the ocular event terms into four clinical categories. Among notifications involving hair-styling pomades, corneal and conjunctival injury or inflammation was led by keratitis (44.7%), which was almost absent among notifications involving other cosmetics (0.8%). Among notifications involving other cosmetics, the most frequent terms were eye irritation (59.2%) and ocular hyperemia (33.8%), both irritative symptoms and signs. Visual disturbances and nonspecific terms were reported in both groups.

Discussion

In this analysis of three national cosmetovigilance systems, notifications involving hair-styling pomades had higher reporting odds of an ocular adverse event than notifications involving other cosmetics, after adjustment for notification year, region, sex, age group, and race/skin color. Keratitis was the most frequent ocular term among pomades, whereas eye irritation and ocular hyperemia predominated among other cosmetics.

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Strengths of this study include the long period covered (2007 through 2025) and the coding of events with a standardized terminology (MedDRA). Its limitations stem mainly from the nature of the data. Spontaneous, routinely collected notifications are susceptible to underreporting, incomplete records, variable field completion, and changes in reporting behavior over time,[6,8] which can distort a disproportionality measure in either direction. Excluding records without recorded sex or age may have introduced selection bias. Duplicates across sources were excluded only for exact one-to-one matches with compatible events, so some notifications may still be counted more than once, inflating counts in either group. Missing or unknown race/skin color limits comparisons across groups. The analysis also lacked data on product sales or use, formulation, batch, application setting, previous ocular history, timing between exposure and symptoms, and treatment, so residual confounding is likely.

The outcome and the product were classified by rules applied to report fields, without clinical confirmation. Ophthalmological confirmation was not systematically available,[13] and ocular events were identified from symptom lists and free text by rules not validated against clinical records, so some misclassification is likely. Notifications involving hair-styling pomades were concentrated in 2023, during an outbreak of chemical ocular injuries linked to hair ointments and of regulatory actions by Anvisa, including safety alerts and a temporary precautionary ban on hair-styling creams.[16] Increased reporting after safety alerts, known as notoriety bias, can raise disproportionality measures;[17] stimulated reporting may therefore have inflated the signal, which should not be generalized to all pomades or periods. Because the data come from Brazilian reporting systems, whose notification practices, product market, and regulatory actions are specific to the country, the findings may not apply to other countries or to other types of hair-styling products.

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Our findings agree with evidence that adverse events related to cosmetics are captured imperfectly by spontaneous reporting but that these systems remain useful for detecting patterns that require public health action,[18-20] and with reviews that emphasize the vulnerability of the eyelids, tear film, and ocular surface to products used near the face.[21,22] They also agree with clinical reports of pain, photophobia, hyperemia, keratitis, and corneal abrasion after exposure to hair-styling pomades during the 2022-2023 outbreak of chemical ocular injuries in Brazil;[23] keratitis, hyperemia, and pain were among the most frequent terms in our data. Unlike case reports, our analysis compares pomades with other cosmetics reported through the same systems, although it cannot estimate incidence. A previous descriptive study by some of the authors examined the regulatory actions taken by Anvisa in response to reports of ocular adverse events related to hair-styling creams between 2022 and 2024;[16] the present analysis adds a comparison with other cosmetics and adjusted estimates over 2007 through 2025.

Stimulated reporting, differences in how events were described across products, and unmeasured product characteristics may have inflated the magnitude of the association, and a disproportionality measure cannot separate these effects from a true effect of the product. A causal mechanism is nevertheless biologically plausible on external evidence. Hair-styling pomades are applied to hair close to the face, often with the hands, and may reach the eye during application, through hand-to-eye transfer, or after mobilization by washing, rain, sweat, or runoff, and reviews of ocular chemical trauma describe epithelial damage, inflammation, and corneal involvement, with early management being important.[24] These data cannot test this mechanism, which should be investigated with clinical and product data.

Modeled probabilities peaked in adolescence, and adjusted odds were higher in adolescents than in adults aged 18 to 44 years but lower in children, despite the high crude proportion of ocular

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events in the youngest group. These age contrasts were not specified in advance and should be read as exploratory. The use of hair products has been reported to increase from childhood to adolescence,[25] which may contribute to the higher odds in adolescents, although that evidence concerns other hair products in a different population. Chemical burns from household and personal-care items, including eye injuries, have been described in young children,[26] so lower adjusted odds in children should not be read as lower vulnerability.

The higher proportion of ocular events among individuals self-identified as Black or Pardo was not retained after adjustment, which suggests that it reflects how products, periods, and regions are distributed among notifications rather than an independent association with race/skin color. Race/skin color was missing for about a third of notifications, and reporting data may also reflect differences in access to services, recognition of adverse events, trust in institutions, and probability of notification.[8,18] Differences in hair-care practices, product choice, and frequency of use by race and ethnicity have been described in other settings[27,28] but cannot be assessed with these data.

The adjusted ROR should not be interpreted as incidence, prevalence, or absolute risk, because the reporting systems do not provide denominators for product use or population exposure.[11,12] It nevertheless indicates that ocular events are reported disproportionately for pomades, which can help prioritize investigation and surveillance.

In conclusion, notifications involving hair-styling pomades were disproportionately associated with ocular adverse events in Brazilian cosmetovigilance data, a signal concentrated in 2023 that cannot be read as incidence or absolute risk. The signal warrants investigation of product formulations and batches, review of labeling, instructions for use, and warning language, and

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attention to professional application practices. Postmarketing monitoring should be able to detect and respond quickly to clusters of ocular injuries, with preventive guidance directed to adult consumers, caregivers, adolescents, and beauty professionals, and with risk communication that is equitable and culturally appropriate. Future studies linking notifications to clinical records, product composition, and sales or use data are needed to confirm the association.

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Author Contributions Statement

Nágyla Cristina Sousa Almeida (NCSA) contributed to conceptualization, data curation, original-draft writing, and review and editing. Daniel Marques Mota (DMM) contributed to resources, supervision, original-draft writing, and review and editing. Carolina Müller Ferreira (CMF) contributed to methodology, original-draft writing, and review and editing. Marcus Tolentino Silva (MTS) contributed to conceptualization, formal analysis, methodology, supervision, original-draft writing, and review and editing. All authors contributed to the article, agree to be accountable for all aspects of the work, and approved the submitted version.

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Data Availability Statement

The data analyzed in this study were obtained from Brazilian health-surveillance adverse-event notification systems maintained by Anvisa. Because the records may contain sensitive or potentially identifiable information about reporters, affected individuals, professionals, establishments, and products, individual-level data are not publicly available. The analysis code and the curated lists of trigger phrases and product names used to classify events and products have been prepared for deposit in SciELO Data. The repository identifier will be added when available. Requests for access to source data should be directed to Anvisa, subject to applicable ethical, legal, and institutional requirements.

Declaration of Use of Artificial Intelligence (AI)

During the preparation of an earlier draft of this work, the authors used OpenAI Codex CLI to assist with English-language editing, LaTeX formatting, and manuscript-structure refinement. During preparation of this submission, the authors used OpenAI Codex CLI and Claude (Anthropic) to assist with reformatting the manuscript to journal submission requirements. The authors reviewed and approved all AI-assisted changes and take full responsibility for the manuscript's content, analyses, interpretations, and conclusions.

Declaration of interest

Daniel Marques Mota is affiliated with the Brazilian Health Regulatory Agency (Anvisa), which maintains the notification systems analyzed in this study. The authors report no other competing interests to declare.

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Tables

Table 1. Characteristics of cosmetic notifications and frequency of ocular adverse events, by selected variables. Brazil, 2007-2025.

Variables and categories	Total, n (% of column)	With ocular adverse event, n (% of category)	p-value
Notification year			<0.001 (chi-square)
2007-2022	611 (16.5)	84 (13.7)	
2023	660 (17.8)	487 (73.8)	
2024	206 (5.6)	99 (48.1)	
2025	2,228 (60.1)	44 (2.0)	
Region			<0.001 (Fisher)
North	104 (2.8)	13 (12.5)	
Northeast	595 (16.1)	130 (21.8)	
Southeast	2,072 (55.9)	517 (25.0)	
South	670 (18.1)	37 (5.5)	
Central-West	251 (6.8)	17 (6.8)	
Missing/unknown information	13 (0.4)	0 (0.0)	
Recorded sex			<0.001 (chi-square)
Male	823 (22.2)	104 (12.6)	
Female	2,882 (77.8)	610 (21.2)	
Age group (years)			<0.001 (chi-square)
0-11	316 (8.5)	136 (43.0)	
12-17	116 (3.1)	57 (49.1)	
18-44	2,373 (64.0)	392 (16.5)	
45-59	646 (17.4)	110 (17.0)	
60+	254 (6.9)	19 (7.5)	
Self-reported race/skin color			<0.001 (Fisher)
White	1,641 (44.3)	125 (7.6)	
Black or Pardo	683 (18.4)	284 (41.6)	
Asian (amarela)	156 (4.2)	19 (12.2)	
Indigenous	11 (0.3)	1 (9.1)	
Missing/unknown information	1,214 (32.8)	285 (23.5)	
Seriousness			<0.001 (chi-square)
Not serious	1,895 (51.1)	102 (5.4)	
Serious	1,810 (48.9)	612 (33.8)	
Reported product			<0.001 (chi-square)
Other cosmetics	3,019 (81.5)	130 (4.3)	
Hair-styling pomades	686 (18.5)	584 (85.1)	

Note: p-value by variable: chi-square = Pearson's chi-square test; Fisher = Fisher's exact test for expected cell counts < 5.

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Table 2. Crude and adjusted associations between notification characteristics and ocular adverse events. Estimates are reporting odds ratios with 95% confidence intervals; values greater than 1 indicate higher reporting odds of an ocular adverse event relative to the reference category.

Variables and categories	Crude ROR (95% CI)	p-value	Adjusted ROR (95% CI)	Adjusted p-value
Notification year		<0.001		<0.001
2007-2022	7.91 (5.43, 11.53)		10.73 (5.92, 19.46)	
2023	139.73 (98.94, 197.33)		8.55 (4.65, 15.73)	
2024	45.93 (30.64, 68.83)		11.28 (5.84, 21.80)	
2025	Reference		Reference	
Region		<0.001		0.174
North	0.43 (0.24, 0.77)		1.73 (0.67, 4.48)	
Northeast	0.84 (0.68, 1.05)		0.85 (0.49, 1.48)	
Southeast	Reference		Reference	
South	0.18 (0.12, 0.25)		0.79 (0.41, 1.51)	
Central-West	0.22 (0.13, 0.36)		0.35 (0.12, 0.98)	
Recorded sex		<0.001		0.798
Male	0.54 (0.43, 0.67)		0.94 (0.58, 1.52)	
Female	Reference		Reference	
Age group (years)		<0.001		0.002
0-11	3.82 (2.98, 4.89)		0.53 (0.30, 0.94)	
12-17	4.88 (3.34, 7.14)		4.42 (1.75, 11.16)	
18-44	Reference		Reference	
45-59	1.04 (0.82, 1.31)		1.23 (0.73, 2.07)	
60+	0.41 (0.25, 0.66)		1.10 (0.43, 2.84)	
Self-reported race/skin color		<0.001		0.991
White	Reference		Reference	
Black or Pardo	8.63 (6.81, 10.95)		0.98 (0.62, 1.57)	
Asian (amarela)	1.68 (1.01, 2.81)		0.95 (0.40, 2.25)	
Reported product		<0.001		<0.001
Other cosmetics	Reference		Reference	
Hair-styling pomades	127.24 (96.74, 167.36)		52.46 (29.18, 94.33)	

Note: ROR denotes reporting odds ratio, and CI denotes confidence interval. P-values represent global tests for each variable block. The adjusted model included notification year, region, recorded sex, age group, self-reported race/skin color, and reported product category. Regressions excluded observations with inconsistent values in model variables, missing/unknown race/skin color, or categories with nine or fewer ocular adverse event notifications; the adjusted model included 2,479 notifications (436 involving hair-styling pomades, 366 with an ocular adverse event; 2,043 involving other cosmetics, 62 with an ocular adverse event). The reference category was the most frequent category of each variable, except for race/skin color (White).

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Table 3. Ocular event terms among notifications with an ocular adverse event (584 involving hair-styling pomades and 130 involving other cosmetics).

Ocular event term	Hair-styling pomades, n (%)	Other cosmetics, n (%)
Corneal/conjunctival injury or inflammation		
Keratitis	261 (44.7)	1 (0.8)
Ocular burn	39 (6.7)	16 (12.3)
Corneal injury	37 (6.3)	3 (2.3)
Conjunctivitis / conjunctival disorder	13 (2.2)	4 (3.1)
Irritative symptoms and signs		
Eye irritation	191 (32.7)	77 (59.2)
Ocular hyperemia	79 (13.5)	44 (33.8)
Eye pain	71 (12.2)	18 (13.8)
Eye swelling	41 (7.0)	36 (27.7)
Increased lacrimation	22 (3.8)	10 (7.7)
Photophobia	8 (1.4)	2 (1.5)
Eyelid disorders	2 (0.3)	0 (0.0)
Visual disturbances		
Vision loss	45 (7.7)	7 (5.4)
Blurred vision	40 (6.8)	3 (2.3)
Visual impairment	9 (1.5)	4 (3.1)
Nonspecific		
Ocular change	75 (12.8)	30 (23.1)
Other ocular event	28 (4.8)	2 (1.5)
Ocular intoxication	6 (1.0)	1 (0.8)

Note: All ocular event terms identified are listed (notifications classified as ocular only through ICD-10 codes or MedDRA terms appear as other ocular event), grouped by clinical category and, within each group, ordered by the number of notifications involving hair-styling pomades and then by total notifications. Percentages are column percentages of notifications with an ocular adverse event in each product group (NOTIVISA, e-Notivisa, and LimeSurvey). A notification may contribute more than one ocular event term, so column percentages do not sum to 100%; n = number of notifications.

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Figures

Figure 1

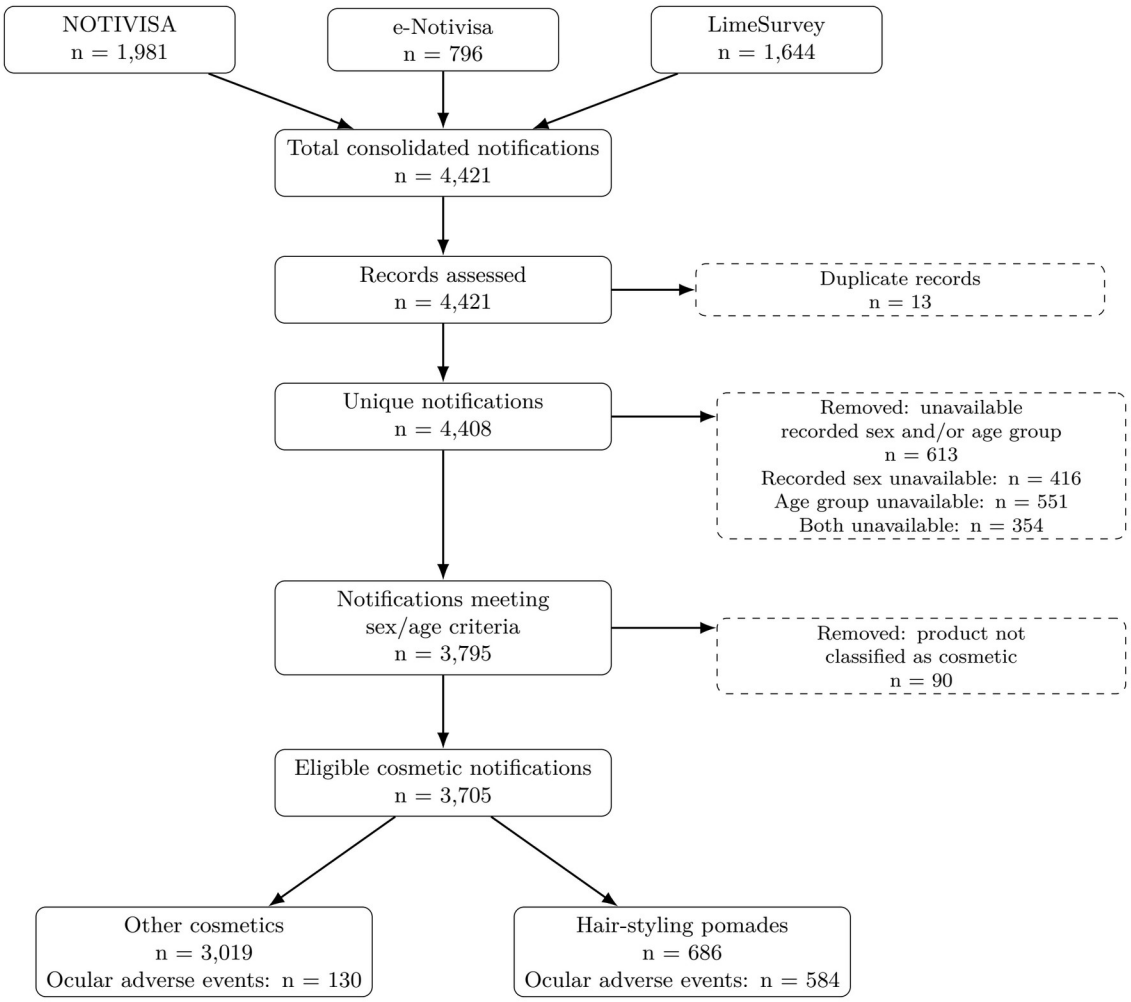

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Figure 2

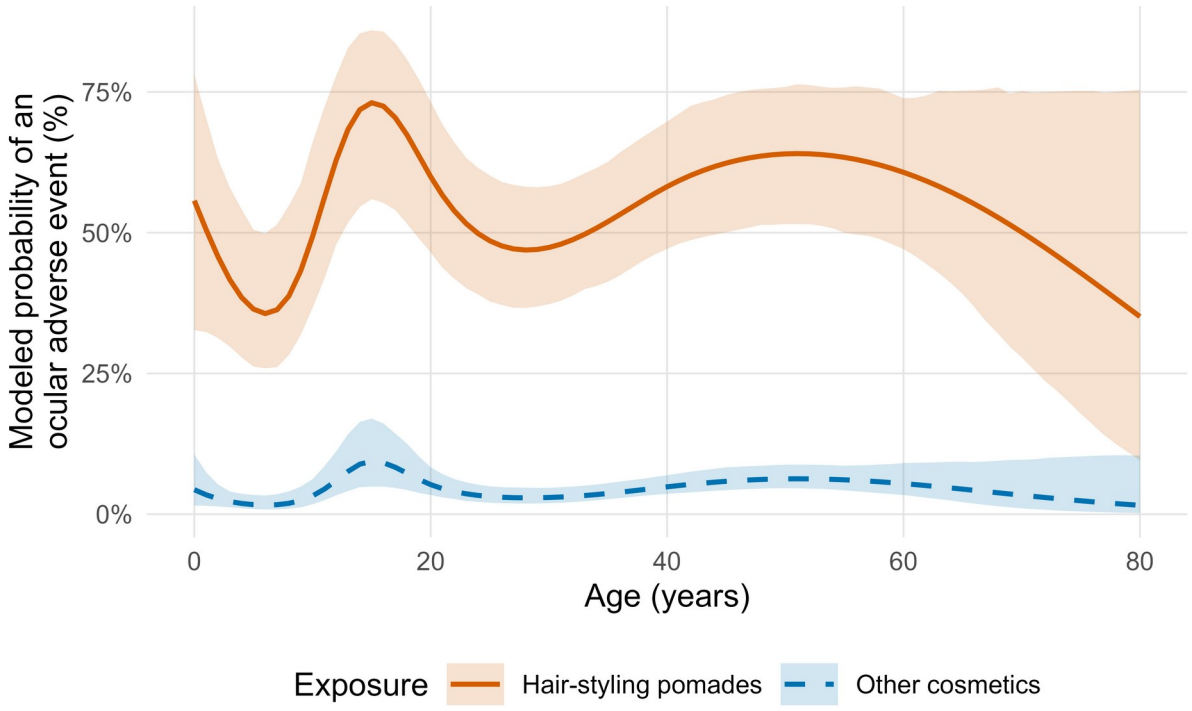

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Figure Captions

Figure 1. Selection flowchart for the analytical sample. The figure shows the number of notifications consolidated from NOTIVISA, e-Notivisa, and LimeSurvey; duplicate records (repeated case identifiers or the same event reported through more than one source); exclusions for unavailable recorded sex and/or age group; exclusions for products not classified as cosmetics; and the final distribution of eligible cosmetic notifications by reported product category and ocular adverse event status. NOTIVISA denotes the Health Surveillance Notification System (Sistema de Notificação em Vigilância Sanitária). Counts for unavailable recorded sex and unavailable age group are not mutually exclusive; “both unavailable” is their intersection. n denotes number of notifications.

Figure 2. Model-adjusted probability that a notification contained an ocular adverse event by age and reported product. The x-axis shows age in years, and the y-axis shows modeled probability of an ocular adverse event in percent. Age was modeled as a natural cubic spline (interior knots at 8, 14, 20, and 40 years) in notifications with a recorded age of 110 years or less; for each age and product, the model-predicted probability was averaged over the notifications in the adjusted model (observed distribution of notification year, region, recorded sex, and race/skin color). Lines show hair-styling pomades (solid orange line) and other cosmetics (dashed blue line). Shaded ribbons represent 95% confidence intervals.

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