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Knowledge brief

Update on children's exposure to isothiazolinones and parabens

RIVM

A. van Leeuwenhoeklaan 9
3721 MA Bilthoven
PO Box 1
3720 BA Bilthoven
www.rivm.nl/en

T 088 689 89 89

Authors:
Jordi Minnema
Femke Affourtit
Gaby Eliesen
Centre:
Centre for Safety of Substances and Products
Contact:
gaby.eliesen@rivm.nl
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Introduction

Isothiazolinones (IT) and parabens are preservatives commonly used in personal care products (PCP), such as shower gel and shampoo. IT are primarily associated with skin sensitisation, whereas parabens are suspected of developmental, reproductive, and endocrine-disrupting effects. There are concerns about possible health effects from exposure to these substances from various consumer products, especially in young children, who are more vulnerable due to a larger body surface area relative to their weight, and increased sensitivity to chemicals.

Consumer exposure to IT and parabens is commonly estimated using two models: ConsExpo (Delmaar & Schuur, 2017) and Probabilistic Aggregate Consumer Exposure Model (PACEM) (Delmaar et al., 2015; Dudzina et al., 2015). ConsExpo is typically used to provide high-end exposure estimates for individual products, although it can also generate more realistic probabilistic exposure distributions for single products. However, it does not account for aggregate exposure from multiple products. In contrast, PACEM is designed to realistically estimate aggregate exposure, but until recently, it lacked product use data for young children. As a result, previous RIVM studies relied on ConsExpo for this group (Affourtit et al., 2022, 2023).

For IT, including methylisothiazolinone (MI), chloromethylisothiazolinone (CMI), and benzisothiazolinone (BIT), cumulative and aggregate exposure sometimes exceeded the acceptable exposure limit (Affourtit et al., 2022). Cumulative exposure refers to the combined exposure to several IT, considering their relative potencies, while aggregate exposure refers to exposure to one substance from multiple consumer products.

For parabens, including methylparaben (MP), ethylparaben (EtP), propylparaben (PrP) and butylparaben (BuP), aggregate exposure to a single type of paraben from different consumer products was lower than the health-based guidance values (Affourtit et al., 2023). Exposures to individual parabens were assessed separately because they differ in potency, metabolism and uncertainties regarding their toxicokinetics and toxicological mechanisms which make it unfeasible to assess their cumulative effects.

Although previous studies provided important insights, they likely overestimated exposure for young children because aggregate exposure was calculated by simply adding conservative estimates for single products. This method results in upper-bound rather than realistic aggregate exposures at the population level.

To improve accuracy, RIVM collected new product use data on PCP used for young children, which has been incorporated into PACEMweb and will be published in the future. Additionally, an internal aggregation tool was developed to combine probabilistic exposure distributions from different assessments, such as ConsExpo, into a single distribution. This approach

takes into account variability in input parameters and better reflects real-life differences between individuals and product use. These new methods enable more realistic aggregate exposure estimates for young children compared to the simple summation method.

Aim of the current study
The aim of the current study is to refine and update the aggregate exposure estimates of young children to IT and parabens in PCP, building on previous work (Affourtit et al., 2022, 2023). To do so, we compare three approaches: (1) aggregated exposure estimates using the updated PACEMweb and recent product use data; (2) aggregating previously derived ConsExpo exposure distributions with the new aggregation tool; and (3) aggregated exposure estimates based on simple summation of previously derived product-specific exposure estimates. This comparison allows us to evaluate the impact of different aggregation methods and to support improved exposure assessment for young children, in line with the objective of the Netherlands Food and Consumer Product Safety Authority (NVWA).

Methods

Product selection
Ficheux et al. (2015) showed that a variety of PCP is used by children aged 0-3 years, which may contribute to their aggregate exposure to chemicals. In previous exposure assessments conducted by RIVM (Affourtit et al., 2022, 2023), PCP were selected based on their use by more than half of children in this age group and the availability of concentration data. To ensure comparability of results, the current study included the same products as in those previous assessments: shampoo, shower gel, and toothpaste.

Product concentration data
To estimate the exposure of children to IT and parabens in PCP using exposure models, data were needed on both the concentrations and their occurrence (the fraction of the products containing the substance of interest). This information was obtained from measurement data collected by the NVWA, as reported in Affourtit et al. (2022, 2023). These reports provided concentrations and occurrences for IT (MI, CMI, BIT) and parabens (MeP, EtP, PrP, BuP). Although the PCP considered are not specifically intended for children, it was assumed that child-specific PCP contain similar preservative concentrations as adult PCP, since preservatives serve the same function in both. Due to lack of IT and paraben concentration data in child-specific PCP, the same data as for adult PCP were used.

For IT, cumulative exposure to MI, CMI and BIT was calculated by converting all concentrations to MI equivalents (MI-eq) using relative potency factors for their sensitising potency (MI: 1, CMI: 40, BIT: 0.04). This approach was used because there is evidence for cross-reaction, where sensitisation by one IT may also trigger elicitation by another (Herman et al., 2019; Schwensen et al., 2017). For parabens, cumulative exposure was not assessed due to lack of information on relative potencies or combined effects. Differences in potency and metabolism, and uncertainties about toxicokinetics and toxicological mechanisms, preclude assessment of cumulative exposures to different parabens. Therefore, exposures to individual parabens were assessed separately.

For parabens, limited concentration measurements in shampoos and shower gels led to pooling these categories, assuming similar function of parabens and likely comparable concentrations. The same concentration and occurrence values were therefore applied to both products.

In PACEMweb and ConsExpo, concentration data were represented as lognormal distributions, but different input parameters were required due to the model interfaces. PACEMweb used the geometric mean and the upper 95% confidence limit of the geometric standard deviation (GSD), while ConsExpo used the median concentration and the arithmetic coefficient of variation (CV). If only one product in a group contained the preservative, a uniform distribution was applied in both models, with boundaries set at ten times lower and ten times higher than the measured concentration. Occurrence was calculated as the fraction of products within a product group containing the preservative. Particularly for small sample sizes, such as for toothpaste, the sample mean and occurrence may be poor proxies for the true values. A summary of concentration and occurrence data used is presented in Table 1.

Table 1 Concentration data and occurrence of MI-eq, MeP, EtP, PrP and BuP used per model for each product based on the values reported by Affourtit et al. (2022) and Affourtit et al. (2023).

Product	Substance	PACEM: Geometric Mean (mg/g) (±GSD)*	ConsExpo: Median (mg/g) (±CV)*	n (Occurrence %)
Shampoo	MI-eq	0.050 (±9.0)	0.17 (±0.80)	226 (8)
	MeP	1.3 (±2.9)	1.1 (±0.62)	446 (4.9)
	EtP	0.65 (±5.9)	1.2 (±0.8)	441 (1.6)
	PrP	0.30 (±9.7)	0.23 (±0.83)	442 (0.68)
	BuP	0.26†	0.26†	441 (0.23)
Shower gel	MI-eq	0.058 (±8.0)	0.13 (±0.78)	253 (6)
	MeP	1.3 (±2.9)	1.1 (±0.62)	446 (4.9)
	EtP	0.65 (±5.9)	1.2 (±0.8)	441 (1.6)
	PrP	0.30 (±9.7)	0.23 (±0.83)	442 (0.68)
	BuP	0.26†	0.26†	441 (0.23)
Toothpaste	MI-eq	—	—	—
	MeP	0.51‡	0.51‡	7 (14)
	EtP	—	—	—
	PrP	—	—	—
	BuP	—	—	—

GSD: Geometric standard deviation; CV: Coefficient of variation; n: Number of samples.
* rounded to two significant digits
† lower boundary = 0.026 mg/g; upper boundary = 2.6 mg/g
‡ lower boundary = 0.051 mg/g; upper boundary = 5.1 mg/g
— Not detected

Exposure calculations

In this study, three approaches were used to estimate the aggregate exposure of children aged 0-3 years to MI-eq, MeP, EtP, PrP, and BuP:

1. PACEMweb: simulates aggregate exposure for both the entire population (users and non-users) and the exposed population (users only), using new survey data for all input parameters.
2. Aggregation tool: aggregates exposure distributions for individual products previously calculated with ConsExpo, without changing input parameters (Affourtit et al., 2022, 2023). This was applied to both populations, specifying the proportion of exposed individuals based on occurrence data.
3. Simple summation: calculates aggregate exposure for the exposed population only, by summing the median and 95th percentiles for individual products from

previous assessments (Affourtit et al., 2022, 2023). This could not be applied to the entire population, as ConsExpo does not provide estimates for non-users.

Table 2 summarises the tools and input parameters used for each approach. For MI-eq, as in the previous study, ConsExpo was used in its traditional worst-case approach, with all input parameters set at the 75th percentile. For parabens, also as in the previous study, a more refined approach was applied by using distributions for use frequency and amount to better reflect real-life variability. This shift in approach for parabens reflects our aim to improve the realism of exposure assessments and is based on insights from the previous MI-eq study.

Table 2 Summary of the tools and input parameters used per study to estimate children's exposure to IT and parabens via PCP

Study	**Tool**	**Substance**	**Body weight, exposed area**	**Frequency**	**Amount per use**	**Population**
Affourtit et al. (2022)	ConsExpo	MI-eq	P75 (te Biesebeek et al., 2014)	P75 (Bremmer et al., 2006)	Adult default (Bremmer et al., 2006), extrapolated to children (Gosens et al., 2014) .	Exposed
Affourtit et al. (2023)	ConsExpo	Parabens	P75 (te Biesebeek et al., 2014)	Log-normal distribution (Ficheux, Dornic, et al., 2016)(P50 and P95)	Log-normal distribution (Ficheux, Chevillotte, et al., 2016)(P50 and P95)	Exposed
Current study	PACEMweb	MI-eq, parabens	New survey data (RIVM)			Entire and exposed
	Aggregation tool	MI-eq, parabens	Exposure distributions from previous ConsExpo assessments without changes in input parameters.			Entire and exposed
	Simple summation	MI-eq, parabens	Median and 95th percentiles from previous ConsExpo assessments without changes in input parameters.			Exposed

Key assumptions and input parameters for each approach are described below. Further details are available in previous assessments, online documentation (Delmaar et al., 2024; Delmaar & Schuur, 2017) or the article outlining the PACEMweb interface (Delmaar et al., 2023).

PACEMweb

PACEMweb simulates individual exposures over a 14-day period, using parameters such as amount per use, frequency, and relevant body surface area, based on new Dutch survey data for children aged 0-3 years (details to be published). Users provide substance concentrations and occurrence, as well as, retention, exposure, and absorption fractions, depending on the substance, health risk, and exposure route.

For IT, the main concern is skin sensitisation, so the relevant metric is *dermal load* (the amount of substance remaining on the skin after product use). PACEMweb uses a retention factor to represent the fraction of the substance that remains on the skin after application. Retention factors of 0.01 g/g were applied for both shampoo and shower gel, and for body sites: head, face, hair, trunk, arms, hands, buttock and legs. Both average (mean over 14 days) and peak (maximum single-day value) dermal loads can be calculated. Because skin sensitisation is triggered by peak exposures, the peak dermal load over the 14-day period was selected for risk assessment.

For parabens, the health concerns are related to chronic systemic effects, such as reproductive toxicity. Therefore, the relevant metric is systemic exposure (the amount that enters the body). PACEMweb uses exposure fractions (the proportion available for absorption via dermal or oral routes) and absorption fractions (the proportion actually absorbed). Exposure fractions were based on SCCS guidance. This was 0.01 g/g for shower gel and shampoo, and 0.4 g/g for toothpaste. The dermal and oral absorption fractions for each paraben are provided in Table 3. These dermal absorption fractions were also used in previous exposure calculations (Gosens et al. (2014) and represent the highest reported values from human skin in vitro studies. For oral exposure, complete absorption (fraction = 1) was assumed for all parabens. Since the risk assessment for parabens considers chronic rather than acute effects, the average systemic exposure (mean over 14 days) was selected instead of the peak system exposure (maximum single-day value).

Table 3 Absorption fractions used to estimate the internal exposure per paraben based on data reported by (Gosens et al., 2014).

	Oral absorption fraction	**Dermal absorption fraction**	**Source (Dermal absorption fraction)**
MeP	1	0.36	Cross and Roberts (2000)
EtP	1	0.55	Cross and Roberts (2000)
PrP	1	0.37	Jewell et al. (2007)
BuP	1	0.42	Cross and Roberts (2000)

Aggregation tool

The aggregation tool was used to aggregate exposure distributions of individual products, as previously generated using ConsExpo with unchanged input parameters from earlier assessments (Affourtit et al., 2022, 2023). Scenarios or input parameters were not updated to reflect the new Cosmetics Fact Sheet (Ashton et al., 2025). For MeP, exposure distributions from shower gel, shampoo, and toothpaste were aggregated. For MI-eq, EtP, PrP and BuP exposure distributions from shower gel and shampoo were aggregated.

Lognormal distributions were used for product concentrations (see Table 1). For MI-eq, all other input parameters (body weight, exposed area, use frequency, and amount) were set at the 75th percentile, representing a reasonable worst-case scenario for dermal load, with variability only in product concentration. For parabens, lognormal distributions were applied for frequency and amount, making systemic exposure estimates more realistic and less conservative than for MI-eq. Input parameters for this approach are summarised in Table 2.

To estimate aggregate exposure, exposure distributions for each product from previous ConsExpo studies were exported and combined using the aggregation tool. Additionally,

to calculate exposure for the entire population, the proportion of individuals exposed to each product group was determined based on the occurrence data in Table 1.

Risk assessment
To estimate the risks associated with aggregate exposure, MI-eq exposures were compared to the Acceptable Exposure Level (AEL) for MI reported in literature (7.4×10^{-2} µg/cm^2) (SCCS, 2015). For parabens, estimated systemic exposures were compared to No Observed (Adverse) Effect Levels (NO(A)ELs) reported in literature. Previous study reported NO(A)ELs of 1000 mg/kg bw/day for MeP, EtP and PrP, and 2 mg/kg bw/day for BuP (SCCS, 2010, 2021). Recently, the NO(A)ELs for MeP and BuP were revised to lower confidence limits of benchmark dose ($BMDL_{5)}$ values: 374 mg/kg bw/day for MeP and 24.5 mg/kg bw/day for BuP (SCCS, 2023a, 2023b, 2025). Margins of exposure (MoE) were calculated by dividing the NOAELs/$BMDL_5$ by the estimated systemic exposures. A MoE of at least 100 (assessment factors of 10 for interspecies and 10 for intraspecies variation) was considered to indicate an acceptable safety margin.

Concerns have been raised about the endocrine-disrupting (ED) potential of parabens at higher exposure levels. According to the SCCS, some data for PrP suggest potential ED effects, but the current evidence is insufficient to classify PrP as an endocrine-disrupting chemical (EDC) or to derive an ED-specific point of departure for risk assessment. Therefore, the NOAEL currently used may not fully account for potential ED effects, and some uncertainty regarding ED risks remains. Additionally, the recently derived BMDLs for MeP and BuP are based on reductions in relative anogenital distance, an endpoint related to anti-androgenic (ED) effects.

Results

Exposure estimates from the two approaches used in this study (PACEMweb and the aggregation tool) are presented in Table 4 and 5. Results are shown for both the entire population (Table 4) and the exposed population (Table 5). While risk assessment typically focuses on the entire population, results for the exposed population are also included to highlight differences between the approaches. In addition, Table 5 shows the summed median and 95th percentile exposures for individual products from previous assessments (Affourtit et al., 2022, 2023) to illustrate the effect of simple summation in comparison to PACEMweb and the aggregation tool.

As visible in Table 4, only a relatively small fraction of the entire population is exposed to MI-eq and parabens. Although this study considers only a limited number of products, it is expected that young children are not exposed to many additional PCP. When comparing the two approaches for the entire population, the estimated 99th percentiles from the aggregation tool are of the same order of magnitude as those from PACEMweb. However, in all cases, PACEMweb resulted in lower estimated exposures than the aggregation tool.

Based on the 95th percentile values of the exposed population (Table 5, Figure 1), the aggregation tool resulted in much lower exposure estimates for PrP (over one order of magnitude lower) compared to PACEMweb. For MeP, EtP and BuP, estimates from both methods were similar (within a factor of three), while for MI-eq, the aggregation tool resulted in higher estimates (less than one order of magnitude difference). Figure 1 illustrates these differences by expressing the 95th percentile estimates from both methods as percentage difference relative to the summation method (set at 100%). Notably, for MI-eq, MeP, and BuP, the 95th percentile estimates using both the aggregation tool and PACEMweb are lower than, or within the same order of magnitude

as, the sum of the 95th percentiles for individual products from previous assessments (Affourtit et al. 2022, 2023). This suggests that summing conservative (high-end) exposure estimates for individual products may overestimate aggregate exposure. However, for EtP and PrP the 95th percentile in the exposed population calculated with PACEMweb exceeded the simple sum of percentiles from previous assessments (Figure 1). This may be due to the high GSD for EtP and PrP in shampoo and shower gel (Table 1), which resulted in high exposures in the higher percentiles.

The 95th percentiles of estimated aggregate dermal loads to MI-eq, as calculated with the aggregation tool (Table 4), exceeds the AEL for MI reported in literature (7.4×10^{-2} µg/cm^2) (SCCS, 2015). In contrast, the estimated aggregate exposure with PACEMweb is below the AEL. For parabens, MoEs were calculated based on the estimated aggregate systemic exposures for each individual paraben. All resulting MoEs exceeded 100, indicating no concern.

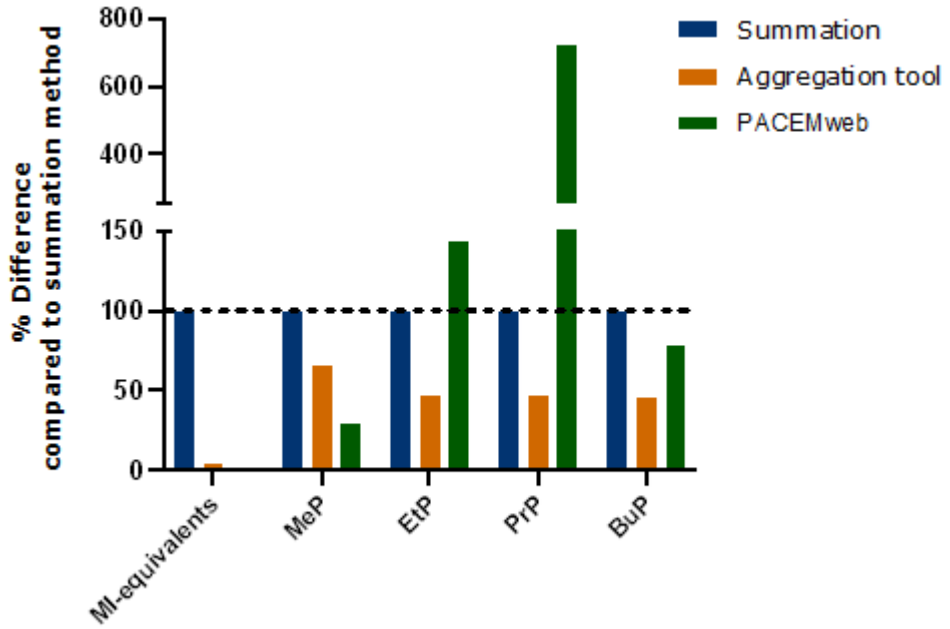
Table 4 Aggregate exposure for parabens and IT in PCP among young children, estimated with PACEMweb and with the aggregation tool based on ConsExpo exposure distributions. The exposure is presented as different percentiles for a population of both non-exposed and exposed individuals. Exposure units are in µg/cm^2 for MI-eq and µg/kg bw/day for parabens. All exposure estimates are rounded to 2 significant values.

Chemical	**Tool**	**P25**	**P50**	**P75**	**P90**	**P95**	**P99**
MI-eq	Aggregation tool	0	0	0	0.036	0.10	0.46
MI-eq	PACEMweb	0	0	0	0.000064	0.0021	0.045
MeP	Aggregation tool	0	0	0	30	95	340
MeP	PACEMweb	0	0	0.00075	11	39	130
EtP	Aggregation tool	0	0	0	0	0	1.9
EtP	PACEMweb	0	0	0	0	0	1.3
PrP	Aggregation tool	0	0	0	0	0	0.045
PrP	PACEMweb	0	0	0	0	0	0.015
BuP	Aggregation tool	0	0	0	0	0	0
BuP	PACEMweb	0	0	0	0	0	0

Table 5 Aggregate exposure for parabens and IT in PCP among young children, estimated with PACEMweb and with the aggregation tool based on ConsExpo exposure distributions. In addition, a simple aggregation was preformed by summing the median and 95th percentiles of previous assessments (Affourtit et al., 2022, 2023). The exposure is presented as different percentiles for a population of only exposed individuals. Exposure units are in µg/cm^2 for MI-eq and µg/kg bw/day for parabens. All exposure estimates are rounded to 2 significant values.

Chemical	**Tool**	**P25**	**P50**	**P75**	**P90**	**P95**	**P99**
MI-eq	Aggregation tool	0.035	0.070	0.15	0.37	0.62	1.6
MI-eq	PACEMweb	0.00040	0.0021	0.011	0.047	0.11	0.53
MI-eq	Summation	-	5.3	-	-	17	-
MeP	Aggregation tool	0.89	22	87	200	320	670
MeP	PACEMweb	1.8	15	44	91	140	240
MeP	Summation	-	79	-	-	490	-
EtP	Aggregation tool	0.34	0.84	2.1	4.3	6.5	15
EtP	PACEMweb	0.19	0.77	3.0	9.9	20	67
EtP	Summation	-	2.4	-	-	14	-
PrP	Aggregation tool	0.041	0.11	0.25	0.55	0.85	1.9
PrP	PACEMweb	0.043	0.24	1.3	5.8	13	67
PrP	Summation	-	0.31	-	-	1.8	-
BuP	Aggregation tool	0.22	0.59	1.4	2.8	3.9	9.0
BuP	PACEMweb	0.39	0.91	2.2	4.5	6.8	12
BuP	Summation	-	1.8	-	-	8.7	-

Figure 1 Comparison of 95th percentile exposure estimates for the exposed population, calculated using the aggregation tool and PACEMweb, expressed as percentage difference relative to the summation method (set at 100%).



Discussion

This study aimed to refine and update aggregate exposure estimates of young children to IT and parabens in PCP, using two new methods: the updated PACEMweb tool, which includes recent Dutch survey data on product use by young children, and the aggregation tool that aggregates exposure distributions for individual products derived using ConsExpo. Aggregate exposure estimates for the exposed population obtained with these methods were compared to a more conservative approach, in which median and 95th percentile exposures for individual products were simply summed.

The results show that both new exposure aggregation methods generally resulted in aggregate exposure estimates for which the high percentiles (95th) are lower than or comparable to, the simple summation of the 95th percentiles of individual products (Table 5, Figure 1). Only for PrP did PACEMweb result in much higher exposure estimates than the summation method, likely due to a greater spread in concentration values for PrP (as reflected in the high GSD). Overall, this indicates that the new methods allow for less conservative aggregate exposure estimates for children compared to the summation method, and offer valuable new possibilities for aggregate exposure assessment in child populations.

When focusing on the entire population (Table 4), the aggregation tool resulted in higher exposure estimates than PACEMweb, particularly for MI-eq. This difference can be attributed to the use of conservative parameter values in ConsExpo when deriving exposure distributions for individual products. Specifically for MI-eq, conservative point values for frequency and amount were used, whereas for parabens, more realistic log-normal distributions were applied. Consequently, the exposure distributions for MI-eq in ConsExpo were more conservative, leading to higher aggregate exposure estimates with the aggregation tool for MI-eq than for parabens. Another reason why PACEMweb

generally produces lower exposure estimates than the aggregation tool may be the way non-users and substance occurrence are handled. PACEMweb accounts for both non-users and occurrence, so a larger proportion of the population is assigned zero exposure, resulting in lower exposure estimates at higher percentiles. In contrast, in the aggregation tool individuals exposed were equated with occurrence. This results in a higher exposure estimate at higher percentiles for the entire population compared to PACEMweb. For the exposed population (Table 5), this difference disappears, as only individuals actually using the products containing the substance are included.

Importantly, because of the difference in the aggregate exposure estimates between both new tools, the risk assessment outcomes for MI-eq vary depending on the aggregation method used. When the aggregation tool was applied, the estimated aggregate dermal load to MI-eq exceeded the AEL, indicating a potential health concern for skin sensitisation in young children. In contrast, the aggregate exposure estimated using PACEMweb was below the AEL, suggesting no health concern. As PACEMweb can be considered more realistic because less conservative assumptions were made for MI-eq compared to the aggregation tool, consequently, aggregate exposure to MI-eq through the products included in this study is expected to be within safe limits.

For parabens, all calculated Margins of Exposure (MoEs) remained well above the threshold of 100, even above 1000, suggesting no immediate health concern. While potential ED effects may not be fully addressed for PrP and EtP due to limited data, these effects have been more thoroughly considered for MeP and BuP. Overall, based on current evidence, this study finds no cause for concern for parabens.

Between the two presented methods, PACEMweb should be preferred, as it utilises product use surveys which typically provide more realistic data than exposure distributions of individual products that are aggregated with the aggregation tool. Moreover, in this study, these exposure distributions were derived using conservative settings in ConsExpo, resulting in relatively high aggregate exposure distributions compared to those estimated with PACEMweb. Nevertheless, the aggregation tool remains very useful, especially if relevant product groups are not available in PACEMweb. In such cases, the aggregation tool enables the aggregation of exposure estimates from other exposure models like ConsExpo with those available in PACEMweb, thus increasing the flexibility of aggregate exposure assessments. For the most realistic results, distributed exposure parameters should be used whenever they are available.

The exposure assessments for MI-eq and parabens conducted in this study yielded results consistent with previous assessments (Affourtit et al. 2022, 2023). This was expected, primarily because the product groups included, namely shampoo, shower gel, and toothpaste, are used daily by a high percentage of young children. When such commonly used products dominate exposure, the co-use effect and the advantages of aggregation tools are less pronounced. In contrast, including less frequently used products would likely increase the impact of these aggregation tools. Furthermore, the effect of the aggregation tool in this study is less notable because only a limited number of product groups were included. If more product groups were assessed, the differences between the results of the new aggregation methods and more conservative aggregation approaches (e.g., summing the 95th percentiles from each group) would likely be greater.

The new Dutch survey data make it possible to perform an exposure assessment for children aged 0-3 years in PACEMweb. Although a wide range of PCP are available in PACEMweb, the majority of products were not included in the current analysis, as relevant

concentration and occurrence data have yet to be compiled. To ensure comparability with previous assessments, this study focused on the same product groups as previously. The survey confirmed that shampoo, shower gel, and toothpaste are most frequently used by children aged 0-3 years, along with baby wipes and diaper ointment. It must be noted that BuP and PrP are prohibited from being used in leave-on products for children and are therefore not expected in products like ointments. In addition, in limited baby wipes samples analysed by the NVWA, IT or parabens were not detected. However, this does not guarantee that these substances are never present in baby wipes, and the lack of comprehensive concentration data has prevented a reliable exposure assessment for this product group in the current study.

As concentration data become available for other product groups, aggregate exposure assessments can be expanded to include more product groups, such as tube creams and hair products. Products like hand cream and face cream were previously assessed for adults but not for children due to low usage in this age group. Now that use data for tube cream are available for children, this product group could be included in future assessments using the same concentration data as for hand cream and face cream for adults.

The updated and more realistic aggregate exposure estimates support the NVWA's objective to improve risk assessments for children. However, persistent data gaps increase the uncertainty in the exposure assessment. A more detailed description and discussion on the uncertainties relevant to the exposure assessment can be found in Affourtit et al. (2022) and Affourtit et al. (2023). Particularly the lack of concentration data for additional product groups and child-specific products highlights the need for continued monitoring and data collection. Expanding both use and concentration data will enable more comprehensive and reliable aggregate exposure assessments, ultimately supporting better protection of children's health.

Conclusion

This study refines and updates aggregate exposure estimates of young children to IT and parabens in PCP by comparing three approaches: the updated PACEMweb tool with new product use data, the aggregation tool based on ConsExpo exposure distributions, and the simple summation of product-specific exposures. Both PACEMweb and the aggregation tool provided lower exposure estimates than the previously used simple summation method. Because of the methodology detailed, these lower exposure estimates are expected to be more realistic.

For the included products, aggregate exposures to parabens estimated with both new methods were within safe limits. Aggregate exposure to each paraben was assessed separately, as cumulative exposure could not be evaluated due to differences in potency and metabolism. For MI-eq, aggregate exposures estimated with the aggregation tool exceeded safety thresholds, whereas those estimated with PACEMweb remained below these thresholds. The aggregation tool resulted in higher estimates because it aggregated more conservative exposure distributions from ConsExpo, which used conservative input parameters. Therefore, aggregate exposure to MI-eq through the included products is expected to be within safe limits.

The main limitation of this study is the small number of products included, due to the lack of concentration data for additional and child-specific products, such as baby wipes and diaper ointment. Continued data collection and monitoring are essential to further improve the reliability of risk assessments and ensure better protection of children's health.

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