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SURVEY AND QUANTITATIVE RISK ASSESSMENT OF PFAS CHEMICALS IN SHAMPOO AND CONDITIONER PRODUCTS

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1. INTRODUCTION

Cardno ChemRisk was asked by WEN By Chaz Dean ("WCD") to conduct a comprehensive risk and safety assessment of the cosmetic product commonly known as WEN® by Chaz Dean Cleansing Conditioner (the "WEN Products"), and, specifically, whether the product causes hair loss and/or any other adverse dermal event. This risk and safety assessment was triggered by complaints and allegations of hair loss by a small percentage of consumers who attributed their alleged hair loss to use of the WEN Products based on anecdotal evidence. As part of the evaluation, Cardno ChemRisk tested the WEN Products for the presence of Per- and polyfluoroalkyl substances (PFAS).

PFAS refers to a group of synthetic chemicals that have been manufactured globally since the 1940s. Production of PFAS historically increased given their desired heat, stain, and water resistance properties, resulting in nearly 5,000 types of PFAS chemicals (FDA 2019). The most common and extensively-studied PFAS chemicals are perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), which are used in the production of various consumer products, including nonstick cookware, food packaging, stain resistant coatings for fabrics and carpeting, cleaning products, and paints (ATSDR 2019).

Several toxicological assessments have evaluated the association between PFAS exposure and various cancer and non-cancer health endpoints. Some toxicological studies have characterized increased health risks in rats upon dietary exposure to PFOA, including tumor growth in the liver, Leydig cells, and pancreas (Biegel et al. 2001; Cook et al. 1992). Rats in high-exposure groups were also shown to have increased risk of liver adenoma in a 2-year feeding study of potassium PFOS (Butenhoff et al. 2012). In 2017, the International Agency for Research on Cancer (IARC) evaluated the association between exposure to PFOA and the risk of various cancer endpoints, reporting that there was "limited evidence" for the carcinogenicity of PFOS in humans. The authors did note a positive association for cancers of the testis and kidney. Overall, IARC concluded that PFOA was "possibly carcinogenic to humans (Group 2B)" (IARC 2017).

PFAS slowly degrade given their strong carbon-fluorine bonds. This ability for PFAS to remain intact over time, paired with the widespread production, has resulted in the environmental persistence of these chemicals in various forms. Potential exposure routes to PFAS include drinking contaminated water, consuming fish from contaminated water, swallowing contaminated dust or soil, eating food that was packaged in PFAS-containing material, and using consumer products (ATSDR 2019) containing PFAS.

There has been recent interest in PFAS levels in personal care and cosmetic products. A previous analysis of the Environmental Working Group's SkinDeep Database identified 13 different PFAS chemicals in nearly 200 products from 28 different brands, including makeup, sunscreen, shampoo, and shaving cream products (Andrews 2018). Further, AB 495, the Toxic-Free Cosmetics Act has been proposed in California, which would prohibit the use of 20 different chemicals in cosmetic products, including PFAS chemicals.

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Given the recently raised concerns about the presence of PFAS in cosmetic products, Cardno Chemrisk tested the potential levels of 23 different PFAS chemicals that are commonly found in the environment in the WEN Products as well as other types of shampoo and conditioner products that are commercially available. We also performed a quantitative risk assessment to calculate potential systemic exposure associated with use of hair care products. This exposure was then compared to exposure from PFAS-containing water during a shower, which is a common method of exposure to PFAS for people as compared to the average population.

2. METHODS

Ten commercially available products were selected for analysis that included: (i) 3 shampoo products ([redacted] shampoo, [redacted] shampoo, and [redacted] shampoo); (ii) three varieties of the WEN Products (Sweet Almond Mint, Lavender, and Pomegranate); and (iii) 4 other cleansing conditioner products ([redacted]

PFAS Quantification

Analytical chemistry was performed to quantify the concentration of 23 different PFAS chemicals in each evaluated product. These PFAS chemicals included 4:2-fluorotelomersulfonic acid, 6:2-fluorotelomersulfonic acid, 8:2-fluorotelomersulfonic acid, NEtFOSAA, NMeFOSAA, perfluorobutanesulfonic acid, perfluorobutanoic acid, perfluorodecanesulfonic acid, perfluorodecanoic acid, perfluorododecanoic acid, perfluoroheptanesulfonic acid, perfluoroheptanoic acid, perfluorohexanesulfonic acid, perfluorohexanoic acid, perfluorononanoic acid, perfluorooctanesulfonamide, perfluorooctanesulfonic acid, perfluorooctanoic acid, perfluoropentanesulfonate, perfluoropentanoic acid, perfluorotetradecanoic acid, perfluorotridecanoic acid, andpPerfluoroundecanoic acid. The concentration of PFAS chemicals was determined by solid phase extraction and liquid chromatography/tandem mass spectrometry (Shoemaker et al. 2008).

As noted later, no PFAS chemicals were detected above the method detection limit (MDL) for all evaluated products. Therefore, the quantitative risk assessment focused only on PFOA, as PFOA is the most well-known PFAS chemical and is considered to be of the most potent PFAS chemicals. For risk assessment purposes, ½ the PFOA MDL was used as the concentration of PFOA in each product. Within each product category (shampoo or conditioner), the range of MDLs was used in the below low and high exposure scenarios.

Consumer Exposure Level

An estimated daily systemic exposure to PFOA among adult women after daily application of shampoo and conditioner products was calculated using the following information: (1) the amount of product applied per application, (2) the number of applications per day, (3) the concentration of PFOA in the product, (4) a retention factor, (5) the surface area of the scalp, (6) the dermal absorption of PFOA, and (7) the body weight of an adult.

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A series of published consumer use practice studies have previously collected data on the amount of product applied and the frequency of use of various personal care and cosmetic products (Loretz et al. 2005; Loretz et al. 2006; Loretz et al. 2009). Specifically, 360 adult women (aged 19-5 years) from 10 different regions in the United States recorded daily usage information for widely used products (including shampoo and conditioner) for a 2-week study period. It was reported that women applied 12.8 grams (mean) or 29.08 grams (95^{th} percentile) of shampoo per application, and applied shampoo 1.11 (mean) or 1.71 (95^{th} percentile) times per day (Loretz et al. 2006). Similarly, it was reported that women applied 13.77 (mean) or 33.19 (95^{th} percentile) grams of conditioner per application, with 1.1 (mean) to 1.4 (95^{th} percentile) applications per day (Loretz et al. 2008). Based on recommended parameters for dermal exposure modeling, the maximum amount of liquid that can adhere to the surface of the skin is 10 mg/cm^2 (Tibaldi 2017). Therefore, the maximum amount of applied product that could adhere to the scalp (maximal dermal exposure [MDE]) was calculated to be 8 grams/applications, based on a scalp surface area of 800 cm^2 (Cadby et al. 2002).

Based on quantitative risk assessment technical guidance documents and literature, we applied a retention factor of 1% for the evaluated shampoo and conditioner products, as both are rinse-off products that do not remain in contact with the scalp skin (SCCS 2017). This accounts for the generally accepted assumption that 1% of the rinse-off product remains on the skin as a residue after rinsing.

Previous analyses have reported that 2% dermal absorption was a conservative estimate of PFAS absorption through human skin as a salt (Fasano et al. 2005; Lassen et al. 2015). For an even more conservative approach, we assumed that the dermal absorption of PFOS was 70%. This is based on data from Franko et al. (2012), which reported that uptake through skin was 23-25% in humans, and that 45% of PFAS acid was detected in the epidermis. Assuming that this 45% of substance could be systemically available, a very conservative assumption of 70% was used.

Health Benchmarks for Risk Assessment

Two No Observed Adverse Effect Levels (NOAELs) were used in this assessment. The first is 0.06 mg/kg bw/day, which was the lowest external oral NOAEL from animal studies (Perkins et al. 2004). Additionally, an external NOAEL of 1 mg/kg bw/day was proposed for PFOA risk assessment (ECHA 2015). Assuming an oral absorption of 93%, these external NOAELs were converted to internal NOAELs of 0.056 mg/kg bw/day and 0.93 mg/kg bw/day, respectively (IARC 2017).

Risk Assessment

A systemic exposure dose (SED) was calculated using the following equation:

$$\text{SED (mg/kg bw/day)} = \frac{(MDE)(A)(RF)(C)(Abs)}{BW}$$

Where:

MDE = maximal dermal exposure (g/application)
A = number of applications per day (applications/day)

RF = retention factor (%)
C = concentration of PFOA (mg/g)
Abs = dermal absorption of PFOA (%)
BW = body weight (kg)

Low and high exposure scenarios were assessed for each product category (shampoo and conditioners). The low exposure scenario used the mean number of applications per day, mean amount of product applied per application, lower dermal absorption value of 2%, lower range of ½ MDL for the concentration of PFOA, and a NOAEL of 0.93 mg/kg bw/day. The high exposure scenario assumed 95th percentile number of applications per day, 95th percentile of product applied per application, higher dermal absorption value of 70%, higher range of ½ MDL for the concentration of PFOA, and a NOAEL of 0.056 mg/kg bw/day.

A margin of safety (MOS) was calculated by dividing the NOAEL by the SED. A MOS was calculated for each exposure scenario for each product category. A MOS >100 indicates that the evaluated product does not pose a risk for consumers under the examined exposure scenario. Using the above equations, we also calculated that concentration of PFOA in shampoos and conditioners that would result in a MOS of 100.

Comparison to Exposure from PFAS-Containing Water

As a comparison, we calculated an individual's exposure to PFOA from water alone during a shower. Similar assumptions were used regarding the retention factor, dermal absorption, body weight, and NOAELs. We assumed the shower water contained the US EPA health advisory level of 70 ng/L (Cordner et al. 2018). Based on the EPA exposure factors handbook, the mean and 95th percentile skin surface area for adult females is 18,140 cm^2 and 22,530 cm^2, respectively. This resulted in maximal dermal exposures of 0.1814 L/application (mean) and 0.2253 L/application (95th percentile), based on maximal adhesion of 10 mg/cm^2 (Tibaldi et al. 2017; EPA 2011). Adult females shower a mean 1.27 times per day (EPA 2011). Based on professional judgment, we assumed that individuals showered for 3 times per day for the high exposure model.

A systemic exposure dose (SED) was calculated using the following equation:

$$\text{SED (mg/kg bw/day)} = \frac{(MDE)(A)(RF)(C)(Abs)}{BW}$$

Where:
MDE = maximal dermal exposure (L/application)
A = number of applications per day (applications/day)
RF = retention factor (%)
C = concentration of PFOA (mg/L)
Abs = dermal absorption of PFOA (%)
BW = body weight (kg)

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3. RESULTS

No PFAS chemicals were detected in any of the evaluated hair care products, including the WEN Products. All 23 PFAS chemicals are listed in Table 1, none of which were detected in any of the evaluated products. The evaluated products and PFOA MDLs are reported in Table 2.

Table 1. PFAS chemicals evaluated in this analysis and detection results for all evaluated products

PFAS Chemical	Result
4:2-Fluorotelomersulfonic acid	Not Detected
6:2-Fluorotelomersulfonic acid	Not Detected
8:2-Fluorotelomersulfonic acid	Not Detected
NEtFOSAA	Not Detected
NMeFOSAA	Not Detected
Perfluorobutanesulfonic acid	Not Detected
Perfluorobutanoic acid	Not Detected
Perfluorodecanesulfonic acid	Not Detected
Perfluorodecanoic acid	Not Detected
Perfluorododecanoic acid	Not Detected
Perfluoroheptanesulfonic acid	Not Detected
Perfluoroheptanoic acid	Not Detected
Perfluorohexanesulfonic acid	Not Detected
Perfluorohexanoic acid	Not Detected
Perfluorononanoic acid	Not Detected
Perfluorooctanesulfonamide	Not Detected
Perfluorooctanesulfonic acid	Not Detected
Perfluorooctanoic acid	Not Detected
Perfluoropentanesulfonate	Not Detected
Perfluoropentanoic acid	Not Detected
Perfluorotetradecanoic acid	Not Detected
Perfluorotridecanoic acid	Not Detected
Perfluoroundecanoic acid	Not Detected

Table 2. Evaluated products, product category, and PFOA detection limit

Brand Name	Product Category	PFOA MDL (ng/g)
[redacted]	Shampoo	2.0
[redacted]		2.0
[redacted]		1.7
WCD Sweet Almond Mint	Conditioner	1.9
WCD Lavender		1.9
WCD Pomegranate		2.0
[redacted]		1.9

[redacted]

[redacted]		1.9
		1.8
		1.9

The parameters used to calculate SEDs for the shampoo and conditioner products are shown in Table 3. Calculated SEDs and MOSs are shown in Table 4. For both shampoos and conditioners, the SEDs were below the NOAELs for both the low and high exposure scenarios. All calculated MOS were >100. Using the above assumptions for the high exposure scenario, PFOA concentrations 0.04% (0.41 mg/g) and 0.05% (0.50 mg/g) were back calculated as the concentrations that would result in MOS of 100 for shampoos and conditioners, respectively. The high exposure scenario was selected over the low exposure scenario in order to be more conservative.

Table 3. Exposure parameters used for shampoo and conditioner products

Product Category	Number of Applications/ Day[a]	Maximal Dermal Exposure (g/ Application)[b]	Retention Factor (%)	PFOA conc. range (mg/g)[c]	Dermal Absorption (%)[d]	Body Weight (kg)[e]
Shampoo	1.11 (mean) 1.71 (95th %)	8	1	$8.5x10^{-7}$ to $1.0x10^{-6}$	2 to 70	70
Conditioner	1.1 (mean) 1.2 1.4 (95th %)	8	1	$9.0x10^{-7}$ to $1.0x10^{-6}$	2 to 70	70

[a]Loretz et al. 2006; Loretz et al. 2008
[b]Cadby et al. 2002; Tibaldi et al. 2017
[c]1/2 the MDLs
[d] Lassen et al. 2015; Franko et al. 2012
[e] EPA 2011

Table 4. Calculated SEDs and MOS by exposure scenario and product category

Product Category	Exposure Scenario[a]	SED (mg/kg bw/day)	NOAEL (mg/kg/bw/day)[b]	MOS
Shampoo	Low	$2.16x10^{-11}$	0.93	$4.31x10^{10}$
	High	$1.37x10^{-9}$	0.056	$4.09x10^{7}$
Conditioner	Low	$2.26x10^{-11}$	0.93	$4.11x10^{10}$
	High	$1.12x10^{-9}$	0.056	$5.00x10^{7}$

[a]Low = mean number of applications/day; lower MDL; 2% absorption; NOAEL 0.93 mg/kg bw/day
High = 95th percentile number of applications/day; higher MDL; 70% absorption; NOAEL of 0.056 mg/kg bw/day
[b]Perkins et al 2004; ECHA 2015; IARC 2017

Exposure to PFOA from Shower Water

The parameters used to calculate SEDs due to exposure to PFOA-containing water during a shower are shown in Table 5. Calculated SEDs and MOSs are shown in Table 6. SEDs from shower water were below the NOAELs for both the low and high exposure scenarios. All

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calculated MOS were >100. Using the above assumptions for the high exposure scenario, a PFOA concentration of 0.0008% (8 mg/L) was back calculated as the concentration in water that would result in MOS of 100. The high exposure scenario was selected over the low exposure scenario in order to be more conservative.

Table 5. Exposure parameters used for PFOA-containing water in a shower

Exposure	Number of Showers/Day[a]	Maximal Dermal Exposure (L/ Application)[b]	Retention Factor (%)	PFOA conc. (mg/L) [c]	Dermal Absorption (%)[d]	Body Weight (kg)[e]
Shower Water	1.27 (mean) 3 (high)	0.1814 (mean) 0.2253 (95th %)	1	$7.0x10^{-5}$	2 to 70	70

[a]EPA 2011; professional judgment
[b]EPA 2011; Tibaldi et al. 2017
[c]US EPA Health Advisory Level
[d] Lassen et al. 2015; Franko et al. 2012
[e] EPA 2011

Exposure	Exposure Scenario	SED (mg/kg bw/day)	NOAEL (mg/kg/bw/day)[a]	MOS
Shower Water	Low	$4.61x10^{-11}$	0.93	$2.02x10^{10}$
	High	$4.73x10^{-9}$	0.056	$1.18x10^{7}$

[a]Perkins et al 2004; ECHA 2015; IARC 2017

The SEDs for exposure to PFOA from shampoos/conditioners vs. shower water alone are shown in Table 7. Exposure to PFOA from shampoos/conditioners was approximately half that of exposure to PFOA from shower water alone in the low exposure model, and approximately a quarter of the exposure to PFOA from shower water alone in the high exposure model.

Exposure	Exposure Scenario	SED	Comparison to Shower Water (%)
Shampoo	Low	$2.16x10^{-11}$	47%
Conditioner		$2.26x10^{-11}$	49%
Shower Water		$4.61x10^{-11}$	NA (100%)
Shampoo	High	$1.37x10^{-9}$	29%
Conditioner		$1.12x10^{-9}$	24%
Shower Water		$4.73x10^{-9}$	NA (100%)

4. CONCLUSIONS

In this analysis perform a survey of various commercially available hair cleansing products, none of which had detectable levels of 23 different PFAS chemicals. This included three varieties of the WEN Products (Sweet Almond Mint, Pomegranate, and Lavender). These findings provide

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further evidence that the WEN Products are not contaminated with any chemicals that may result in adverse health effects.

Additionally, this analysis demonstrates a proactive screening for PFAS in advance of upcoming regulation in California. These findings suggest that the WEN Products would be in compliance with PFAS levels in cosmetic products.

This study also performed a quantitative risk assessment for the evaluated shampoo and conditioner products. All of the evaluated products, including the WEN Products, had calculated systemic exposure dose levels that were below the no adverse effect levels, resulting in margins of safety above 100. This is indicative that use of the product would not be expected to cause adverse health effects in consumers due to PFOA exposure. This was even true in the highly conservative model that assumed the 95th percentile number of applications per day, a dermal absorption of 70%, and use of the lowest animal NOAEL.

Further, findings from this study show that potential exposure to PFOA (despite it not even being detected) from the evaluated hair cleansing products is approximately 50-75% lower than the exposure to PFOA from shower water alone. Overall, findings from this analysis provide evidence that exposure to PFAS chemicals is not expected to occur among users the WEN Products.