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SURVEY OF CONSTITUENTS USED IN CONSUMER AND PERSONAL CARE PRODUCTS

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Prepared by:

Andrew Monnot, Ph.D.
Cardno ChemRisk – Managing Health Scientist

Ernest Fung, Ph.D., DABT
Cardno ChemRisk-Supervising Health Scientist

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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, which evaluation was triggered by complaints and allegations that the Products caused hair loss in a small percentage of consumers. As part of that comprehensive risk and safety assessment, Cardno ChemRisk has engaged in an analysis to identify consumer and personal care products that are currently on the market that contain constituents used in the three best-selling versions of the Products (Sweet Almond Mint, Lavender, and Pomegranate), which are the three most complained about of the Products, and to evaluate the safety of said constituents.

This analysis is a recognized method of determining the safety of a cosmetic product. Indeed, the Food and Drug Administration (FDA) has stated that cosmetic manufacturers may use available safety data on individual ingredients or products with similar formulations to assess the safety of the ingredient (FDA 2016). Similarly, according to the European Commission's Scientific Committee on Consumer Safety (SCCS), the safety of a cosmetic product is based on the safety of its ingredients (SCCS 2016). So, the fact that ingredients in the WEN Products are contained in other cosmetic products on the market is a factor in determining that the WEN Products are safe. This is especially important because, while a wide range of consumer and personal products are sold on the market by a large number of manufacturers, all of those products are commonly formulated from a limited number of constituents and/or ingredients.

2. METHODS

The first step in this analysis was to review the constituent and formulation information for the three best-selling and most complained about versions of the WEN Products (Sweet Almond Mint, Lavender, Pomegranate), which were provided by WCD and has been summarized in Table 1. WCD confirmed that, for the WEN Products manufactured by WCD, these formulations have not changed since the product entered the marketplace (although WCD has informed us that its licensee, the direct marketing company, Guthy-Renker, LLC, which separately manufactures the WEN Products made one change to the formulations that replaced Kathon CG with phenoxyethanol and ethylhexylglycerine, but our analysis only involved WCD manufactured the WEN Products). These three versions of the WEN Products contain most of the ingredients used in all versions of the WEN Products.

The next step was to review available information regarding "safe level" of use, or the level at which an ingredient or constitutent is considered safe for use in cosmetics. Information on the chemical ingredients were collected and incorporated from various databases and textbooks, many of which are created and maintained by regulatory agencies and all are the authoritative sources relied upon by the scientific community in determining human health risks from exposures to chemicals, cosmetic ingredients, food, and drugs. This included the following:

- PubMed

- Medline

- Google Scholar.

The searches were done with combinations of the following key words were used: <ingredient name> and safety, toxicity, safe levels, and level of use. Electronic searches were supplemented with additional relevant studies or publications obtained by manual review of the bibliographies of retrieved publications. Additionally, FDA's generally recognized as safe (GRAS) database was reviewed to identify constituents that were "generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use" (FDA 2017).

The third step was to assess how prevalent the 33 chemicals and compounds found in the WEN Products are in commonly used personal care products. To accomplish this, we utilized two publicly-available databases: the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database.

The National Library of Medicine's Household Products Database was initially compiled in 1995 and is based on the Consumer Product Information Database by DeLima Associates. Information in the Household Products Databases is derived from multiple publicly-available sources including brand-specific labels and Safety Data Sheets from manufacturers. This database was last updated in September 2016.

The EWG's Skin Deep Cosmetics Database was initiated in 2004 and utilizes label information provided to them by companies and manufacturers. To ensure that the database contains the most current products on the market, EWG automatically categorizes any product that has been in the database for longer than three years as an old formulation; if the products have not been verified within the last six years, the products are removed from the database. EWG categorizes products into one or more of 130 product categories.

Within each database, we utilized Chemical Abstracts Service (CAS) numbers (the most authoritative collection of disclosed substance information) when available to retrieve product information for each compound. Product results for lavender extract and lavender oil were combined, and no search results were found for methyl 2-nonynoate, resulting in 31 chemical or compound categories. The product search results for each compound were then tabulated into a spreadsheet and were categorized into 58 specific product categories and 28 general product categories. Products that could potentially fall into more than one category (i.e. a 2-in-1 shampoo & conditioner) were retained for each applicable category; otherwise, duplicate products within each database and among the two databases were removed from the final product list. It should be noted that the overall total product counts per compound is inclusive of duplicates due to product category-crossover.

In the National Library of Medicine's Household Products Database Product, lists were available for all 31 compounds from this database and were tabulated in a spreadsheet. The results were filtered to only include personal care products. Products that were identified as "old product" or "discontinued" in the product listing were excluded. In addition, as these product listings were

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categorized as “personal care products,” each product was manually re-categorized into one of the aforementioned 58 categories. In many instances, the product type was evident from the product name; however, for products with ambiguous or unclear names, an additional search was conducted with general search engines (i.e. Google) to clearly identify the product. It should be noted that the list may contain outdated products that were not identified as such in the parent database.

In the EWG’s Skin Deep Cosmetics Database, product lists for all 31 compounds were found in this database and tabulated in a spreadsheet. Although specific categories were provided for each product, there was a significant level of overlap and disorganization in categorization such that one product may be categorized as “Shampoo” and “New Category // smoothing & frizz control // smoothing & frizz control //” and “salon shampoos // New Category // smoothing & frizz control // smoothing & frizz control //.” With the intent to capture all products available per compound, all data entries across all EWG categories were tabulated and duplicative results were eliminated.

3. RESULTS

Based on the review of the National Library of Medicine’s Household Products Database and the EWG’s Skin Deep Cosmetic Database, more than 20,000 consumer and personal care products were found to contain one or more of the listed constituents or combination thereof that are contained in the WEN Products. Information obtained from reviewing the National Library of Medicine’s Household Products Database and the EWG’s Skin Deep Cosmetic Database were sorted by constituent into 28 pre-determined categories and is summarized in Table 2. Information regarding individual products that contain one or more of the listed constituents is detailed in Appendix 1. A summary of each ingredient detailing its frequency of use and a comparison to derived safe use concentrations by the CIR or other organizations.

Aloe Vera Leaf Juice

Aloe barbadensis is commonly referred to as Aloe vera (IARC 2016). Treatment of whole leaf Aloe vera extract by activated carbon can remove the anthraquinone compounds responsible for the bitterness and color of the latex, resulting in a “decolorized whole leaf extract”; the properties of the decolorized leaf differ from those of the whole leaf (IARC 2016). Aloe Vera Leaf Juice is used in approximately 3000 personal care products in the National Library of Medicine’s Household Products Database and the EWG’s Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 487 body wash, face wash, and exfoliant products; 206 conditioners; 98 foundation, powder, beauty balm, and concealer products; 657 moisturizer, cream, lotion, and body oil products; and 281 shampoos (Table 2). The reported concentration range of aloe vera leaf juice used in WCD products is 0.3 to 1 percent.

Amodimethicone

Amodimethicone is a member of the dimethicone family of silicone products, which is characterized by their methylated linear siloxane polymer units (Yahagi 1993; Nair 2003). Dimethicones are widely used in conditioners, hair care, skin care, and other cosmetic products as a result of their lubricating and water-insoluble properties (Yahagi 1993). Additionally,

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dimethicones are used as food additives (Nair 2003). Amodimethicone is used in approximately 1000 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 4 body wash, face wash, and exfoliant products; 409 conditioners; 7 foundation, powder, beauty balm, and concealer products; 5 moisturizer, cream, lotion, and body oil products; and 218 shampoos (Table 2). The reported concentration range of amodimethicone used in WCD products is 0.3 to 1 percent. The CIR reported a safe level of use of up to 15 percent in cosmetic products (Nair 2003).

Avocado Oil

Persea grattisima oil is a mixture of fatty acids, including primarily oleic, palmitic, linoleic, and palmitoleic acids derived from the fruits/seeds of an avocado tree (Belsito, Hill et al. 2011). It is used in approximately 1500 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 144 body wash, face wash, and exfoliant products; 127 conditioners; 85 foundation, powder, beauty balm, and concealer products; 398 moisturizer, cream, lotion, and body oil products; and 68 shampoos (Table 2). [redacted]

Behentrimonium Methosulfate

Behentrimonium methosulfate is a member of the trimonium compound family with a straight alkyl chain 22 carbons in length and is not water soluble due to the long alkyl chain (Becker, Bergfeld et al. 2012). It is used in approximately 500 consumer products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 10 body wash, face wash, and exfoliant products; 301 conditioners; 46 moisturizer, cream, lotion, and body oil products; and 10 shampoos (Table 2). [redacted] According to the CIR, behentrimonium methosulfate has a safe level of use up to 10 percent in cosmetic products (Becker, Bergfeld et al. 2012).

Cetearyl Alcohol

Cetearyl (aka cetostearyl) alcohol is a straight-chain aliphatic alcohol, mostly compromised of cetyl and stearyl alcohols (Elder 1988). It is used in approximately 4000 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 178 body wash, face wash, and exfoliant products; 921 conditioners; 80 foundation, powder, beauty balm, and concealer products; 1410 moisturizer, cream, lotion, and body oil products; and 59 shampoos (Table 2). [redacted]

Cetyl Alcohol

Cetyl alcohol, also known as 1-hexadecanol or n-hexadecyl, is a 16 carbon straight-chain aliphatic alcohol (Elder 1988). It is used approximately 3000 personal care products in the National Library

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of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 167 body wash, face wash, and exfoliant; 717 conditioners; 27 foundation, powder, beauty balm, and concealer products; 1089 moisturizer, cream, lotion, and body oil products; and 171 shampoos (Table 2). [redacted] According to the CIR, cetyl alcohol is considered safe in the present practice of use in cosmetics (Elder 1988; Panel 2008).

Chamomile Extracts

Chamomilla recutita, or chamomile, is a well-known medicinal plant species from the Asteraceae family (Singh, Khanam et al. 2011). The best-known botanical name for chamomile is Matricaria recutita (Singh, Khanam et al. 2011). It is used in over 1,200 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 264 moisturizer, cream, lotion, and body oil products; 203 body wash, face wash, and exfoliant products; 142 shampoos; 100 conditioners; and 100 foundation, powder, beauty balm, and concealer products (Table 2). [redacted] The CIR Expert Panel concluded that Chamomilla recutita is considered safe in the present practices of use and concentration in cosmetics when formulated to be non-sensitizing (Belsito, Klaassen et al. 2013).

Citric Acid

Citric acid is a white solid that is soluble in water and some organic solvents (Soccol, Vandenberghe et al. 2006; Fiume, Heldreth et al. 2014). It is widely used as a flavor, fragrance, pH adjuster, chelating agent, skin conditioning agent, and buffering agent in foods, beverages, cosmetics, pharmaceuticals, detergents and cleaning products, and pesticides due to its low toxicity (Soccol, Vandenberghe et al. 2006; Fiume, Heldreth et al. 2014). It is used in approximately 6500 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 1142 body wash, face wash, and exfoliant products; 856 conditioners; 89 foundation, powder, beauty balm, and concealer products; 650 moisturizer, cream, lotion, and body oil products; and 1590 shampoos (Table 2). [redacted] The CIR panel concluded that citric acid was considered safe in the present practices of use and concentration in cosmetic products (Fiume, Heldreth et al. 2014). Additionally, citric acid is generally regarded as safe by the U.S. FDA (FDA 2017).

Cucumber Extract

Cucumus sativus, also known as cucumber, fruit extract has been reported to function as an emollient skin-conditioning agent in cosmetic products (Belsito, Hill et al. 2012). Cucumber fruit consists of 96% water and the remaining constituents include vitamins, minerals, amino acids, phytosterols, phenolic acids, fatty acids, flavonoids, terpenoids, tannins and cucurbitacins (Belsito, Hill et al. 2012). Cucumber extract is found in approximately 700 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 119 body wash, face wash, and

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exfoliant products; 14 conditioners; 65 foundation, powder, beauty balm, and concealer products; 187 moisturizer, cream, lotion, and body oil products; and 21 shampoos (Table 2). [redacted]

Dicetyldimonium Chloride

Dicetyldimonium chloride is also known as dicetyldimethylammonium chloride; it is a quaternary ammonium salt, and is classified as a surfactant, conditioning agent, emulsifier and antistatic agent for cosmetic use (ChemIDplus 2016; SpecialChem 2016). It is found in approximately 200 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 135 conditioners; 2 moisturizer, cream, lotion, and body oil products; and 7 shampoos (Table 2). [redacted]

Guar Hydroxypropyltrimonium Chloride (GHC)

GHC is also known as guar gum, 2 hydroxy-3-(trimethylammonio) propyl ether, chloride (Johnson Jr, Heldreth et al. 2015). It is found in approximately 1300 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 160 body wash, face wash, and exfoliant products; 301 conditioners; 2 foundation, powder, beauty balm, and concealer products; 7 moisturizer, cream, lotion, and body oil products; and 728 shampoos (Table 2). [redacted]

Glycerin

Glycerin, also known as glycerol, is a clear, syrupy liquid, and is completely miscible with water, methanol, ethanol, and other alcohols (Becker, Bergfeld et al. 2015). It is found in approximately 10,000 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 1692 body wash, face wash, exfoliant products; 743 conditioners; 745 foundation, powder, beauty balm, and concealer products; 2519 moisturizer, cream, lotion, and body oil products; and 821 shampoos (Table 2). [redacted] The CIR concluded that use of glycerin in cosmetic products was safe in the present practices of use and concentrations (Becker, Bergfeld et al. 2015). Additionally, glycerin was generally regarded as safe by the U.S. FDA (FDA 2017).

Lavender Extracts

Lavandula angustifolia, or lavender, is a species of flowering plant native to the Mediterranean region, the Arabian peninsula, and Russia (Health 2016). It is used in over 2,300 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 721 moisturizer, cream, lotion, and body oil products; 534 body wash, face wash, and exfoliant products, 171 shampoos; 180 miscellaneous skin products which includes but is not limited to facial serums,

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facial masks, and massage oils; and 117 conditioners (Table 2). The reported concentration range of lavender flower and lavender oil used in WCD products is 0.01 to 0.1 percent and 0.1 to 0.3 percent, respectively. Lavender is generally regarded as safe by the U.S. Food and Drug Administration (FDA 2017).

Marigold Extracts

Calendula officinalis, or marigold, is an annual plant native to the Mediterranean region (Cordova, Siqueira et al. 2002). It is used in over 1,000 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 296 moisturizer, cream, lotion, and body oil products; 164 body wash, face wash, and exfoliant products; 96 shampoos; 66 conditioners; and 71 miscellaneous skin products, which includes but is not limited to facial serums, facial masks, and massage oils (Table 2). The reported concentration range of marigold used in WCD products is 0.01 to 0.1 percent. The CIR Expert Panel concluded that calendula officinalis-derived ingredients are safe for use in cosmetics in the practices of use and concentration (Andersen, Bergfeld et al. 2010).

Methychlorolisothiazolione (MCI)

MCI is one of two active ingredients in cosmetic preservative Kathon ((SCCS) 2009). It is used in approximately 2500 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 368 body wash, face wash, and exfoliant products; 649 conditioners; 8 foundation, powder, beauty balm, and concealer products; 42 moisturizer, cream, lotion, and body oil products; and 976 shampoos (Table 2). [redacted] The CIR concluded that MCI was considered safe in rinse-off cosmetic products up to 100 ppm, and in leave-in products when formulated to be non-sensitizing (Belsito, Klaassen et al. 2014). Additionally, according the manufacturer's recommendations, the maximum use level for Kathon is 0.1% by weight (15 ppm active ingredient) in rinse-off products such as shampoos and hair conditioners and 0.05% by weight (7.5 ppm active ingredient) in leave-on products such as skin creams and lotions (Haas 2007; DOW 2013).

Menthol

Menthol is a cyclic terpene alcohol naturally present in the volatile oil of plants from the Mentha species including peppermint and cornmint oil; menthol can also be synthesized artificially (Galeotti, Mannelli et al. 2002; Patel, Ishiuji et al. 2007; Kumar, Baitha et al. 2016). It is used in approximately 750 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 110 body wash, face wash, and exfoliant products; 94 conditioners; 36 foundation, powder, beauty balm, and concealer; 39 moisturizer, cream, lotion, and body oil products; and 114 shampoos (Table 2). [redacted] Menthol is generally regarded as safe by the U.S. FDA (FDA 2017; FDA 2017).

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Methylisothiazolione (MI)

MI is one of two active ingredients in cosmetic preservative Kathon (SCCS 2009). It is used in approximately 3000 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 460 body wash, face wash, and exfoliant products; 719 conditioners; 63 foundation, powder, beauty balm, and concealer; 130 moisturizer, cream, lotion, and body oil products; and 1016 shampoos (Table 2). [redacted] The CIR concluded that MI was considered safe in rinse-off cosmetic products up to 100 ppm, and in leave-in products when formulated to be non-sensitizing (Belsito, Klaassen et al. 2014). Additionally, according the manufacturer's recommendations, the maximum use level for Kathon is 0.1% by weight (15 ppm active ingredient) in rinse-off products such as shampoos and hair conditioners and 0.05% by weight (7.5 ppm active ingredient) in leave-on products such as skin creams and lotions (Haas 2007; DOW 2013).

Panthenol

Panthenol is the pro-vitamin alcohol analogue of pantothenic acid that when applied topically, is rapidly converted to pantothenic acid (Vitamin B5) (Stables and Wilkinson 1998; Camargo Jr, Gaspar et al. 2011). It is used in approximately 500 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 20 body wash, face wash, and exfoliant products; 79 conditioners; 18 foundation, powder, beauty balm, and concealer; 51 moisturizer, cream, lotion, and body oil products; and 77 shampoos (Table 2). [redacted] The CIR Expert Panel concluded that panthenol is safe as presently used in cosmetic products (Johnson 1987; CHLORIDE and CHLORIDE 2006). Additionally, panthenol is generally regarded as safe by the U.S. FDA (FDA 2017; FDA 2017).

PEG-60 Almond Glycerides

PEG-60 almond glycerides is a polyethylene glycol derivative of the mono- and diglycerides from almond oil with an average of 60 moles of ethylene oxide (Burnett, Heldreth et al. 2014). It is used in approximately 50 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 1 body wash, face wash, and exfoliant products; 1 conditioners; 1 foundation, powder, beauty balm, and concealer; 2 moisturizer, cream, lotion, and body oil products; and 13 shampoos (Table 2). [redacted]

Polysorbate-60

Polysorbate 60, also known as sorbitan monostearate, ethoxylated, is used in cosmetic and personal care products as a fragrance ingredient, surfactant-emulsifying agent, and surfactant solubilizing agent (Becker 2015). It is used in approximately 800 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 55 body wash, face wash, and exfoliant products; 118 conditioners; 48 foundation, powder, beauty balm, and concealer; 293 moisturizer, cream, lotion,

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and body oil products; and 12 shampoos (Table 2). [redacted] The CIR concluded that polysorbate-60 was considered safe to use in cosmetic products when formulated to be non-irritating (Becker 2015).

Pomegranate Extract

Punica granatum, or the pomegranate, is a shrub or small fruit-bearing tree native from Iran to the Himalayas in northern India (Morton 1987). Pomegranate extract is used in approximately 800 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 202 lip products; 198 moisturizer, cream, lotion, and body oil products; 19 conditioners; 22 shampoos; 70 foundation, powder, beauty balm, and concealer products; and 65 body wash, face wash, and exfoliant products (Table 2). [redacted] Pomegranate is generally regarded as safe by the U.S. FDA (FDA 2017).

Rosemary Extract

Rosmarinus Officinalis, or rosemary, is an evergreen bushy shrub native to the Mediterranean coast and sub-Himalayan areas (Al-Sereiti, Abu-Amer et al. 1999). It is used in approximately 1700 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 394 moisturizer, cream, lotion, and body oil products; 280 body wash, face wash, and exfoliant products; 207 lip products, 159 shampoo products; and 140 conditioners (Table 2). [redacted] Rosemary is generally regarded as safe by the U.S. FDA (FDA 2017).

Soy Protein

Hydrolyzed soy proteins are produced from isolated soy proteins that have been hydrolyzed with a protease enzyme for two hours (Belsito, Hill et al. 2015). It is used in over 500 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 168 conditioners; 162 shampoos; 60 moisturizer, cream, lotion, and body oil products; and 57 miscellaneous hair products (Table 2). Based on available data, no signs of systemic toxicity were observed with oral exposures to greater than 2000 mg/kg hydrolyzed soy protein (Belsito, Hill et al. 2015). Soy proteins are used as food, and daily exposure from food use would result in much larger systemic exposures than from use in cosmetic products. [redacted] The CIR Expert Panel concluded that soy-based ingredients are considered safe in cosmetics (Belsito, Hill et al. 2015).

Starch

Wheat starch is a natural product obtained from milled grain of wheat, *triticum vulgare*. It is used in the formulation of bath, body and hand, hair, and skin cleansing products due to its capacity to absorb liquid (Info 2017). It is used in over 50 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table

[redacted]

2). Specifically, it is used in approximately 5 body wash, face wash, and exfoliant products; 6 conditioners; 1 moisturizer, cream, lotion, and body oil products; and 2 shampoos (Table 2). [redacted] The CIR Expert Panel concluded that wheat starch is considered safe to use as cosmetic ingredients (Info 2017).

Stearamidopropyl Dimethylamine

Stearamidopropyl dimethylamine is physically characterized as a waxy flake that functions as an antistatic agent and hair conditioning agent in cosmetics (Belsito, Hill et al. 2014). It is used in approximately 600 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 324 conditioners; 1 moisturizer, cream, lotion, and body oil products; and 13 shampoos (Table 2). [redacted] According to the CIR, stearamidopropyl dimethylamine is safe to use in cosmetic products when formulated to be non-sensitizing (Belsito, Hill et al. 2014).

Sweet Almond Oil

Prunus Amygdalus Dulcis, or sweet almond oil, is a type of vegetable oil that is used in over 1,500 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it was found in 557 moisturizer, cream, lotion, and body oil products; 227 body wash, face wash, and exfoliant products; 204 lip products; 72 shampoo products; and 96 conditioners (Table 2). According to a 2011 report from the Cosmetics Ingredient Review, there were 1,127 reported uses for sweet almond oil and its concentration of use ranged from 0.0001 to 77 percent (Belsito, Hill et al. 2011). [redacted] The CIR Expert Panel concluded in their 2011 report that sweet almond oil was safe in regards to its present practices of use and concentration.

Tetrasodium EDTA

Ethylenediaminetetraacetic acid tetrasodium salt (EDTA) is one of many EDTA salts that are commercially available (EPA 2004). It is used in approximately 2500 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 580 body wash, face wash, and exfoliant products; 218 conditioners; 154 foundation, powder, beauty balm, and concealer; 241 moisturizer, cream, lotion, and body oil products; and 711 shampoos (Table 2). [redacted]

Wheat Protein

Hydrolyzed wheat protein are widely used in the composition of current products of western lifestyle (Laurière, Pecquet et al. 2006). It is prepared either from insolubilized total flour proteins or more generally only from gluten (Laurière, Pecquet et al. 2006). It is used in over 700 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is found in approximately 177

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conditioners; 168 shampoos; 102 hair styling products; and 84 miscellaneous hair products (Table 2). [redacted] The CIR Expert Panel concluded that hydrolyzed wheat protein are safe in cosmetics when formulated to minimize peptide lengths greater than 30 amino acids (Belsito, Hill et al. 2014).

Wild Cherry Extract

Prunus serotina, or wild black cherry, is a fruit-bearing tree known both for its hard, strong wood, making it sought after in furniture and cabinet-making, as well its fruits, which when pitted are eat raw or used in the production of wine and jellies (Nesom 2017). As an extract, it appears to not be commonly used in personal care products as it was only found in seven hair styling products, four shampoos, three conditioners, and one body wash, face wash, and exfoliant products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). [redacted] While wild cherry bark is generally recognized as safe by U.S. FDA, it is unclear if this is inclusive of the fruit extract (FDA 2017).

Witch Hazel

Hamamelis virginiana, also known as witch hazel, is a deciduous, tall shrub, or small tree; natural witch hazel is considered one of the few plant products that meet FDA standards for safety and effectiveness (Agency 2009). It is used in approximately 400 personal care products in the National Library of Medicine's Household Products Database and the EWG's Skin Deep Cosmetic Database (Table 2). Specifically, it is used in approximately 48 body wash, face wash, and exfoliant products; 10 conditioners; 12 foundation, powder, beauty balm, and concealer; 74 moisturizer, cream, lotion, and body oil products; and 18 shampoos (Table 2). [redacted] Witch hazel is generally regarded as safe by the U.S. FDA (FDA 2017).

4. DISCUSSION AND CONCLUSION

This analysis demonstrated that the 30 constituents used in the WEN Products (Sweet Almond Mint, Lavender, and Pomegranate) are commonly used in a wide variety of consumer and personal care products. Although few constituents had specific safe level thresholds, more than half of the listed constituents were considered safe in the present practice and use by the CIR. Additionally, approximately one third of these constituents were generally recognized as safe by the FDA.

Although the two publicly available databases that were reviewed were extensive and well established, the scope of this analysis is limited to the number of consumer and personal care products listed in these databases. It is likely that a number of consumer and personal care products were not included in these two databases. Additionally, new products that are introduced onto the market may not be added to these databases immediately. Thus, it is fair to assume that the total number of consumer and personal care products containing the listed constituents will be greater than the number listed in this analysis.

[redacted]

Based on the number of consumer and personal care products that contain the listed constituents and the available safe level information, we conclude that the constituents used and the concentrations of these ingredients in the WEN Products are similar to other personal care products on the market. As recognized by the FDA guidelines, this is a significant factor demonstrating the WEN Products are safe and not likely to cause an adverse dermal event.

5. REFERENCES

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