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HEAT STRESS DEGRADATION OF WCD SWEET ALMOND MINT CLEANSING CONDITIONER

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1. INTRODUCTION

Cardno ChemRisk was asked by WEN By Chaz Dean, Inc., ("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 WEN Products caused hair loss in a very small percentage of consumers. As part of that risk and safety assessment, through a search of the scientific and/or medical literature, we identified potential causes of hair loss and/or any other adverse dermal event, and then tested the WEN Products to determine whether such potential cause could have been induced by use of the Products. One such potential cause for an adverse event was degradation of the WEN Products due to heat stress from common hair tools such as a hair dryer or curler or flat press. To test for this, we performed a degradation analysis following high heat stress on a recent batch of the best-selling version of the WEN Products (Sweet Almond Mint). The purpose of this analysis was to determine whether any changes to the WEN Products, including the formation of any additional chemicals, occurred upon heat stress associated with its use.

2. BACKGROUND ON CHEMICAL STABILITY

Chemical stability is a key component of ensuring that a personal care or cosmetic product is safe for consumer use. Current industry recommendations for stability testing of cosmetic products considers whether foreseen conditions experienced during transport, storage and handling impacts the integrity of the product. Physical and chemical stability is typically conducted under elevated temperatures up to 45°C for several months to simulate potential storage conditions. However, such testing procedures may not reflect temperature stressors experienced during the actual conditions of product use. For example, hair care products, including shampoos and conditioners remaining on the hair and skin, may be exposed to high-heat stress from the styling processes of blow-drying or straightening. Average temperatures experienced during the use of such styling equipment may reach 60°C or 185°C, respectively (Lee et al. 2011; Breuning et al. 2008; Dussaud et al. 2013). Since chemical reactions are accelerated at elevated temperature, chemical alterations may occur in a product remaining on the skin or hair subjected to high heat stress, subjecting consumers to exposures to unanticipated chemical(s).

3. METHODS

Two batches of the best selling WEN Products (Sweet Almond Mint cleansing conditioner) (Lot #95744, manufacture date 9/2016 and Lot #96346, manufacture date 9/2016) were randomly selected and provided directly to the analytical laboratory from the manufacturer and stored at ambient conditions until the time of analysis. All chemical testing was performed by Avomeen Analytical Services (www.avomeen.com; Ann Arbor, MI), an FDA registered testing facility. For analytical measurements, product samples were prepared in parallel, with one sampled heated to the specified temperature and the other remaining at room temperature. Samples were heated in an incubation oven for 15 min to simulate the use of a hair dryer (60°C; Lot #95744) or

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flatiron straightener (185°C; Lot #96346) and allowed to cool to room temperature. Paired unheated and heated samples were analyzed via reverse phase high-performance liquid chromatography (HPLC), gas chromatography-mass spectroscopy (GC-MS), and fourier transform infrared spectrometry (FT-IR).

The resulting spectra from each paired sample set were compared to identify any changes in chemical composition and/or new degradation products resulting from heating.

4. RESULTS AND DISCUSSION

Several peaks were detected in the HPLC chromatograms for all samples. The number of peaks, retention time, and peak area for each sample were found to be reproducible based on triplicate injection. There were no significant differences in the spectra of paired unheated and heated samples, with heating to 60°C or 185°C. Similarly, several peaks were detected and identified in the GC-MS chromatograms for all samples. The number of peaks, retention time, and peak area for each sample were found to be reproducible based on triplicate injection. Small changes in peak heights of several chemical constituents were observed in the sample heated to 60°C compared to the unheated sample, while no changes were observed upon heating to 185°C. Importantly, no new peaks were identified in either of the heated samples.

No significant changes were observed in spectra obtained from FT-IR analysis between paired unheated and heated samples upon heating to 60°C. Some small changes in signal intensity were observed in the sample heated to 185°C compared to the unheated sample. These changes were considered insignificant as the FT-IR analysis was not designed for quantitative analysis.

5. CONCLUSIONS

We performed a degradation analysis following high heat stress on a recent batch of the WEN Products Sweet Almond Mint cleansing conditioner. Our results show that no significant changes in chemical composition were observed upon heating of the WEN Products Sweet Almond Mint cleansing conditioner. In particular, no additional peaks were observed in our analysis of samples heated to 60°C or 185°C, indicating that no degradation products were formed following high temperature stress. These results suggest that consumers would not be exposed to any unforeseen chemical(s) formed as a result of product degradation from high temperatures experienced during consumer use of the product.

6. REFERENCES

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