



ENDOTOXIN TESTING OF WEN CLEANSING CONDITIONERS



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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 comprehensive 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 hair loss identified in the literature that is the subject of this report was endotoxin contamination.

Endotoxins, often referred to as pyrogens, are a group of biologically active components secreted by gram-negative bacteria (Culbertson et al. 1980). Bacterial endotoxins, made up of heat stable components of the outer wall, are chemically diverse and are collectively referred as lipopolysaccharides (LPS) (Culbertson et al. 1980). Exposure to endotoxins may lead to a variety of adverse events, including activation of the immune system, induction of blood coagulation, metabolic effects, neurological effects, hepatotoxicity, inflammation, skin reactivity, and death (Culbertson et al. 1980; Raetz et al. 2002; Watson et al. 1963).

Although not well defined, skin reactivity response to endotoxin exposure including hypersensitivity, inflammation, Shwartzman reaction, necrosis, and psoriasis also has been reported (Watson et al. 1963; Sveen 1977; Penington et al. 2006). Hypersensitivity reaction of the immune system was reported following exposure to 10 ug of endotoxin applied to rabbit skin in an animal study (Watson et al. 1963). Primary skin inflammatory reaction quantified by skin lesions in rabbit skin was reported after exposure to 0.39 ug LPS (Sveen 1977). Local Shwartzman reaction, characterized by necrosis, interstitial hemorrhage, and thrombosis was reported after exposure to 10 and 25 ug of LPS in rats and rabbits respectively (Penington et al. 2006; Sveen 1977). Psoriasis, a chronic immune-mediated skin inflammatory disease was reported in patients on rare occasions following endotoxin exposure; however, the specific level of endotoxin exposure was not reported (Gaspari 2006; Rosenberg et al. 1982; Belew et al. 1982). These examples illustrate the potential dermal toxicity following endotoxin exposure, justifying the need for endotoxin testing and the production of endotoxin-free cosmetic products.

2. METHODS

Endotoxin screening of Sweet Almond Mint cleansing conditioner manufactured by WEN was performed by Associates of Cape Cod, a GMP compliant, ISO registered, and DEA licensed endotoxin testing facility. The bacterial endotoxin test was performed in accordance to USP guidelines in compliance to FDA regulations (USP 39, NF 34 (2016) Chapter 85; 21 CFR 210.1; 21 CFR 211.1). Random samples of WEN Sweet Almond Mint Cleansing Conditioner tested included current production batch (Lot # 95743), samples manufactured six months ago (Lot # 92783), as well as samples manufactured three to five years prior (Lot # 71589).

3. RESULTS AND CONCLUSION

Endotoxin concentrations were not detected in any of the three random cleansing conditioner samples tested:

Table 1. Endotoxin testing results for Sweet Almond Mint Cleansing Conditioner

Sample Identification	Endotoxin Concentration	Limit of Detection
Current production sample	Not detected	<1.6 EU/mL
6 month old sample	Not detected	<6.3 EU/mL
3 to 5 year old sample	Not detected	<3.1 EU/mL

These endotoxin testing results suggest that the samples were manufactured in a sterile environment with sterile ingredients and contamination was not observed. Additionally, the lack of endotoxin in aged samples suggest that the product remains in good condition with a shelf life of a minimum of, at least, five years. More importantly, the lack of endotoxin in all tested random samples implies that the alleged hair loss or any other adverse dermal effects, if present, following exposure to the cleansing conditioners were not due to contamination of the WEN Products by endotoxins or the presence of bacterial endotoxins.

4. REFERENCES

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