Evaluation Summary of Oakmoss Absolute for Use as a Cigarette Ingredient

Oakmoss extracts (concrete, absolute, absolute co-distillates, resinoids, and essential oils) are obtained from the lichen, Evernia prunastri, which grows on trunks and branches of oak trees.[1,2] Over one hundred constituents have been reported to be present in oakmoss extracts; however, factors such as availability of oakmoss, addition of other moss types, types of solvent(s) used, and additional processing steps affect the presence or absences of various constituents.[1,3] Oakmoss has been in use for thousands of years as a fragrance,[4] and continues to be used in cosmetics and perfumery products,[1,5] with only minor use in food.[6,7] Oakmoss has been recognized as GRAS (generally recognized as safe) for use in food by US Food and Drug Administration (21 CFR §172.510) and the Flavor and Extract Manufacturers Association (FEMA No. 2795) [6] and is approved for use by the Council of Europe (CoE No. 194) with limits on camphor and thujone.[8]

Limited toxicity information on oakmoss extract(s) was found in the available literature, however, oakmoss is relatively non-toxic with an oral LD50 of 2.9 g/kg in rats.[9] Numerous studies have demonstrated the ability of oakmoss, and cosmetics containing oakmoss, to elicit an allergic reaction in humans.[10-17] In one human study, oakmoss absolute was prepared with the following constituents removed: atranol, chloroatranol, ethyl hematommate, and ethyl chlorohematommate. This modified extract did not elicit an allergic response in the 100 subjects tested.[16] No reports of an allergic reaction to oakmoss from consuming food were found in the literature. Oakmoss constituents of primary concern are alpha- and beta-thujone, although a study quantifying the amount of thujones in oakmoss extract was not found in the literature. In a safety assessment by the Burdock Group,[18] the assertion is made that if oakmoss is composed of 10% thujones (an overestimate) and the consumption of oakmoss is 0.0001694 mg/kg/day, then the potential exposure to thujones from foods containing oakmoss is calculated to be 0.000017 mg/kg/day, which is greater than 100,000-fold less than the estimated no observed effect level (5 mg/kg) for inducing convulsions in animals by thujones.[19] Therefore, it is improbable that this adverse effect to thujones would occur from consuming foods containing oakmoss.[18]

Oakmoss absolute is applied directly to tobacco as a flavoring material. Oakmoss absolute is currently used worldwide at levels below 100 ppm in selected cigarette brands manufactured and/or distributed by Philip Morris USA Inc. (PM USA) and/or Philip Morris Products SA (PMP SA). As such, oakmoass absolute may be subject to pyrolysis-type reactions when smoked. Oakmoss absolute may also be applied to the filter as a flavoring material where it would not be subjected to pyrolysis temperatures.

Purge and trap analysis conducted by PM USA indicates that a small portion of oakmoss absolute would be expected to distill at 100°C.[20] At the higher temperatures used in pyrolysis studies conducted by PM USA, results offered further evidence that oakmoss absolute would be pyrolyzed extensively and would not be delivered in the smoke intact.[21]

Oakmoss absolute was part of a PM USA testing program that was designed to evaluate the potential effects of 333 ingredients added to typical commercial blended test cigarettes on selected biological and chemical endpoints.[22-25] Three pairs of test cigarettes were produced, each containing different groups of ingredients. Oakmoss absolute was added to one pair at target levels of 6 ppm and 19 ppm. No significant effects were noted in cytotoxicity, mutagenic

studies or in respiratory tract endpoints in 90-day rat inhalation studies. In addition, smoke chemistry studies from cigarettes containing a mixture of flavors including oakmoss absolute did not significantly alter the smoke chemistry profile compared to control cigarettes. Based on the results of these studies, the authors concluded that these ingredients (including oakmoss absolute) added to tobacco do not add significantly to the overall toxicity of cigarettes.

Currently, information is only available for tests utilizing oakmoss absolute in a mixture of ingredients applied to cigarette tobacco. Studies are ongoing to address the use of oakmoss absolute as a single ingredient and at higher tobacco application levels. Published studies show there is no meaningful difference in the composition or toxicity of smoke from cigarettes with added ingredients (including oakmoss absolute up to 125 ppm[26]) compared to the smoke from cigarettes without added ingredients.[22-30] Based on the best available data, the ingredients used in PM USA and/or PMP SA cigarettes do not increase the overall toxicity of cigarette smoke.

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