Evaluation Summary of Benzoin Resinoid for Use as a Cigarette Ingredient

Benzoin resinoid, also called benzoin gum, $(CAS No. 9000-05-9)^1$ is used in the food industry as a flavor ingredient and coloring agent. U.S. Food and Drug Administration (FDA) has approved benzoin resinoid for use in food as a flavoring agent and adjuvant with no restrictions on food categories (21 CFR § 175.510). FDA has also approved benzoin resinoid as a color additive for use in fruits and vegetables (21 CFR § 73.1). It has been recognized as GRAS (generally recognized as safe) for use in food by the Flavor and Extract Manufacturers Association (FEMA No. 2133),¹ and it is approved for use by the Council of Europe (CoE No. 439).² Several constituents have been identified in benzoin resinoid; the important constituents include benzoic and cinnamic acids (up to 39%), vanillin, coniferyl benzoate and resin esterified with benzoic acid, styrol and styracin.³

Although benzoin resinoid has been in use for about a century and is approved for food uses, few studies evaluating its toxic effects were found in the scientific literature. Benzoin resinoid has a very low acute oral and dermal toxicity in laboratory animals.^{4,5} The dermal exposure (skin application) studies with benzoin oil in guinea pigs showed that this material produced minimal cutaneous irritation, but may be a sensitizer.⁶ When tested in humans, benzoin resinoid did not produce irritation or sensitization reactions.⁷⁻⁹ However, a number of cases of sensitization and cross sensitization to benzoin resinoid have been observed in individuals sensitive to other balsams or other benzoin mixtures (*i.e.* compound tincture of benzoin, which is mixture of benzoin, aloe, storax and tolu balsam in alcohol).^{10,11}

Currently, benzoin resinoid is 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). Benzoin resinoid is primarily used in cigarettes as a tobacco flavoring ingredient where it may be subject to distillation and/or pyrolysis. Benzoin resinoid may also be applied to the filter as a flavoring material where it would not be subjected to pyrolysis temperatures.

Purge and trap studies were conducted by PM USA by heating benzoin resinoid to 100 °C and measuring the resulting vapor phase, suggest that a small portion of benzoin resinoid applied to cigarette tobacco would be expected to distill.¹² Pyrolysis studies conducted with benzoin resinoid exposed to higher temperatures were consistent with the purge and trap results indicating volatilization of vanillin, ethanol and benzoic acid. The remaining peaks indicate pyrolytic destruction of benzoin resinoid.¹³

Benzoin resinoid 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.¹⁴⁻¹⁷ Three pairs of test cigarettes were produced, each containing different groups of ingredients. Benzoin resinoid was added to two pairs at target levels of 11 ppm, 32 ppm, 153 ppm and 460 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 benzoin resinoid did not significantly alter the smoke chemistry profile compared to control

¹ Other CAS numbers are 9000-73-1 and 91845-21-5

cigarettes. Based on the results of these studies, the authors concluded that these ingredients (including benzoin resinoid) added to tobacco do not add significantly to the overall toxicity of cigarettes.

Currently, information is only available for tests utilizing benzoin resinoid in a mixture of ingredients applied to cigarette tobacco. Studies are ongoing to address the use of benzoin resinoid as a single ingredient. Published studies show there is no meaningful difference in the composition or toxicity of smoke from cigarettes with added ingredients (including benzoin resinoid) compared to the smoke from cigarettes without added ingredients.¹⁴⁻²¹ 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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