## **Evaluation Summary of Rum for Use as a Cigarette Ingredient**

Rum is "generally recognized as safe" (GRAS) for use as a food ingredient by the Food and Drug Administration (FDA).<sup>1</sup> While the primary use of rum is as an alcoholic beverage, it is also used in food as a flavoring ingredient, especially in dessert-type foods. Rum is manufactured by the distillation of fermented sugar cane, although the exact process varies between countries and even distilleries. The two basic steps that produce rum are (1) the addition of yeast to sugar cane, or its by-products and conversion into alcohol by fermentation and; (2) distillation of the fermentation products to separate desirable volatile components from undesirable components. Rum is typically produced in countries that produce sugar cane, including but not limited to Australia, South Africa, Reunion, Central America and the United States.<sup>2</sup>

There are over 100 flavoring constituents associated with rum and toxicity data are not available on the effects of these constituents.<sup>3</sup> The constituent of greatest concentration in rum is ethanol.<sup>4</sup> Although there is an extensive database of data on the effects of ethanol, toxicity information on ethanol will not be included in this summary because rum is being used here as a flavoring ingredient, not as an alcoholic beverage. Several acute studies in rats have found that rum inhibits gastric acid output. However, this effect was attributed to the ethanol content and not the rum flavoring constituents.<sup>5,6</sup> Rum was found to produce a weak mutagenic response in the Ames assay and it was found to be mutagenic in the Ara test (forward mutation assay using Salmonella).<sup>7,8</sup> Rum was found to increase the number of dose dependent Sister Chromatid Exchanges in human peripheral blood lymphocytes.<sup>9</sup> In humans, the most significant effect of rum is acute intoxication due to excessive consumption.

Rum is applied directly to the tobacco as a flavoring material. Currently, rum is used worldwide at levels below 110 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, rum, may be subject to pyrolysis-type reactions when smoked. Rum may also be applied to the filter as a flavoring material where it would not be subjected to pyrolysis temperatures.

As suggested by purge and trap studies conducted by PM USA, the volatile components of the rum mixture, ethanol and propylene glycol (propylene glycol is used as a denaturant in rum), will completely distill prior to the burning cone and therefore significant amounts of these volatile components would not be available for pyrolysis.<sup>10</sup> At the higher temperatures used in PM USA pyrolysis studies, the same two compounds (ethanol and propylene glycol) were identified.<sup>11</sup>

Rum 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. Three pairs of test cigarettes were produced, each containing different groups of ingredients. Rum was added to two pairs of test cigarettes at target levels of 40, 87, 120 or 261 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 rum 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 rum) added to tobacco do not add significantly to the overall toxicity of cigarettes.<sup>12</sup>

Currently, information is only available for tests utilizing rum in a mixture of ingredients applied to cigarette tobacco. Studies are ongoing to address the use of rum 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 rum) compared to the smoke from cigarettes without added ingredients.<sup>12-20</sup> 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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