Evaluation Summary of Lovage Extract for Use as a Cigarette Ingredient

Lovage (*Levisticum officinale* Koch) is a herb that grows wild in temperate zones around the world. The plants including the roots exhibit a strong celery-like odor and therefore essential oils as well as oleoresins are produced from the leaves, seeds, and roots.[1] The terms lovage oil and lovage extract are used interchangeably to identify the steam distillation product derived from lovage plant roots.[2]

Lovage and its extraction products have a long history and widespread use as flavoring substances, fragrance materials and herbal medicinals.[3] Lovage extract has been recognized as GRAS (Generally Recognized As Safe) for use as a flavor ingredient by U.S. Food and Drug Administration (21 CFR §172.510) and Flavor and Extract Manufacturers Association (FEMA No. 2650).[4]

A limited toxicological database exists for lovage oil/extract. Lovage is relatively non-toxic following acute exposure by oral and dermal routes.[3] With the exception of occluded application to rabbit skin, lovage extract was generally non-irritating and non-sensitizing in animal studies and on human volunteers.[3] No genetic toxicology or repeat dose animal studies on lovage or extracts were found in an extensive search of the literature.[5]

Currently, lovage extract 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). Lovage extract is applied directly to cigarette tobacco or tobacco stems as a flavoring material. As such, lovage extract may be subject to pyrolysis-type reactions when smoked. Lovage extract may also be applied to the filter as a flavoring material where it would not be subjected to pyrolysis temperatures.

As suggested by the purge and trap studies conducted by PM USA, when lovage extract is added to tobacco, phthalide isomers, primary constituents of lovage extract, would be expected to distill at 100°C.[6] At the higher temperature used in the pyrolysis studies conducted by PM USA, lovage extract produced a number of individual chemical entities, including some pyrolysis products such as phenol and acetaldehyde.[7] The formation of small amounts of these materials is not unexpected, since pyrolysis of organic materials may lead to formation of these compounds. The pyrolysis results also implied that phthalides, the primary aromatic and taste components in lovage extract,[8,9] would be delivered in the smoke relatively intact.[7] The results of these analyses suggest that when lovage extract is applied to cigarette tobacco, the phthalides would be delivered in the smoke relatively intact, with no extensive pyrolysis of lovage extract.

Lovage extract 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.[10-13] Three pairs of test cigarettes were produced, each containing different groups of ingredients. Lovage extract was added to two pairs as part of the ingredient mixture at target levels of 3, 10, 37, and 109 ppm on tobacco. 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 lovage extract 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 lovage extract) added to tobacco do not add significantly to the overall toxicity of cigarettes.

Currently, information is only available for tests utilizing lovage extract as part of an ingredient mixture. Studies are ongoing to address the use of lovage extract 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 lovage extract) compared to the smoke from cigarettes without added ingredients.[10-16] Based on the best data available, the ingredients used in PM USA and/or PMP SA cigarettes do not increase the overall toxicity of cigarette smoke.

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