

**Evaluation Summary of
Clary oil
for Use as a Cigarette Ingredient**

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INTRODUCTION

Clary oil (CAS # 8016-63-5) is currently used worldwide at levels below **5 ppm** in selected cigarette brands manufactured and/or distributed by Philip Morris International. Clary oil is applied directly to the tobacco as a flavoring material. As such, clary oil may be subject to pyrolysis-type reactions when smoked. Clary oil may also be applied to the filter as a flavoring material where it would not be subjected to pyrolysis temperatures. This document summarises our internal studies and current published toxicology information on clary oil abstracted from online toxicity databases.

TOXICITY DATA ON UN-BURNED MATERIAL

Overview

Clary oil is used in the food industry as a flavor ingredient. Clary oil is a pale yellow or pale olive colored liquid with a sweet herbaceous and tenacious odor and a soft and somewhat bittersweet undertone reminiscent of ambra. Perfumers have described the oil to have a tobacco-like, balsamic or tea-like odor that resembles cistus oil and Moroccan chamomile.¹ The oil is obtained from clary sage, *Salvia sclarea* L. (Family Labiatae or Lamiaceae), a perennial or biennial aromatic plant thriving in temperate regions.^{2,3} The plant was used by the Greeks and Romans for medicinal purposes, and clary oil continues to be used in alternative medicines today.^{2,4-7} In the 1500s it became popular for addition to food and beverages.^{5,8} Because of its unique flavor, a combination of sage and mint with a coriander note, clary continues to be used in Europe for seasoning various foods and wines.^{1,9} The United States Food and Drug Administration (21 CFR §182.20, 582.20), the Flavor and Extract Manufacturers' Association (FEMA No. 2321)^{10,11}, the International Organization of Flavor Industries¹² and the Council of Europe (CoE No. 415){CoE, 1981 241 /id} approve clary oil for food use.

Health hazard data

Two unpublished studies reported the acute oral toxicity in rats as 5.0 – 6.2 g/kg, while the acute dermal toxicity in rabbits was > 2 g/kg.¹³⁻¹⁵ Moderate amount of skin irritation was reported from the use of full strength clary sage oil applied to the intact or abraded rabbit skin and maintained under occlusion for 24 hours.¹⁴ However, in 24- and 48-hour closed patch test studies with humans, there were no positive reactions identified from use of full strength clary oil or clary oil in 8% petrolatum. Further, there were no sensitization reactions observed in volunteers tested with 8% clary oil in petrolatum.^{13,16,17}

TOXICITY DATA ON BURNT MATERIAL

Combustion studies

As suggested by the purge and trap studies conducted by PM USA¹⁸ clary oil applied to tobacco would be expected to distill at 100°C. At the higher temperatures used in pyrolysis studies conducted by PM USA, results indicated that remaining clary oil would not be pyrolyzed and would be delivered to the smoke relatively intact.¹⁹

Philip Morris ingredient testing program

Clary oil 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.²⁰⁻²³ Three pairs of test cigarettes were produced, each containing different groups of ingredients. Clary oil was added to one pair at target levels of 3 and 9 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 clary oil 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 clary oil) added to tobacco do not add significantly to the overall toxicity of cigarettes.

CONCLUSION

Cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers. Smokers are far more likely to develop serious diseases, like lung cancer, than non-smokers. There is no "safe" cigarette. Government health warnings about smoking apply to all cigarettes, regardless of the ingredients added, including those containing only tobacco and paper.

The results of this evaluation of clary oil involving a review of published information and internal studies show there is no meaningful difference in the composition or toxicity of smoke from cigarettes with added ingredients (including clary oil) compared to the smoke from cigarettes without added ingredients.²⁰⁻²³ It is our scientific judgement, based on the best available data, that clary oil used in our cigarettes does not increase the overall toxicity of cigarette smoke.

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