

Evaluation of
Chamomile Flower Oil, Hungarian
For Use as an Ingredient in
Tobacco Products

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INTRODUCTION

Chamomile flower oil, Hungarian (German) (CAS # 8002-66-2 or 8053-34-7) is currently used worldwide at levels up to **100 ppm** in selected brands of tobacco products manufactured and/or distributed by Philip Morris International, including cigarettes and fine-cut tobacco. This document is a review of the published toxicology information on chamomile flower oil, Hungarian abstracted from online toxicity databases.

Overview^a

Chamomile flower oil, Hungarian (German), is used in the food industry as a flavour ingredient^[1]. Hungarian-type chamomile oil is obtained by steam-distillation of the flowers and stalks of *Matricaria chamomilla* L^[2]. The oil is used as a flavour ingredient in a majority of the food categories, including alcoholic and non-alcoholic beverages, baked goods, frozen dairy and gelatine^{[1],[2]}. Chamomile oil is reported to contain large amounts of an alcohol, bisabolol (~50%)^{[3],[4],[5],[6],[7]}.

Confusion abounds regarding the use of the scientific name of the chamomile plant. Although the currently accepted scientific name for Hungarian (German) chamomile is *M. recutita*^[8], other names such as *C. recutita* and *M. chamomilla* are still commonly used in the literature^{[9],[10]}. To add to this confusion, another chamomile, Roman or English from the plant *Chamaemelum nobile* (formerly *Anthemis nobilis*) is not distinguished separately in several reports^{[10],[11]}. However, both of the plants belong to the family *Compositae* (now *Asteraceae*).

As a food flavouring additive, the material has been assessed under the provisions of the *Federal Food, Drug and Cosmetic Act, section 201 (s)*, by the Expert Committee of the USA Flavour and Extract Manufacturers Association (FEMA), to be generally recognised as safe (GRAS) under current conditions of use.

The use of this ingredient on tobacco products is regulated in several countries worldwide. It is approved for use in tobacco products as an additive or flavouring in several countries with Tobacco Product Regulations, including e.g., Belgium, Croatia, Czech Republic, Egypt, Finland, France, Germany, Great Britain, Hungary, Lithuania, Macedonia, Romania, Slovak Republic, Spain, Switzerland. Apart from countries that approve its use, there is no country, regardless of the extent to which tobacco products are regulated therein, that affirmatively prohibits the use of this ingredient on tobacco products.

^a Note: Philip Morris International shares the concerns of regulators and the public health community about the proliferation of certain cigarette brands that have a predominantly candy-like or fruity flavour and are particularly appealing to minors, and we support legislation that would ban such cigarettes. However, there is currently no consistent terminology used by regulators and the public health community to describe such cigarettes. This can lead to confusion and potential for misinterpretation. In this document, any references to flavours or "smoke aroma" or flavour perceptions such as "sweet", "fruity", etc. are not meant to describe a flavour, taste or aroma that would dominate the taste of the final product, let alone dominate it in a way that is appealing to minors. Rather, such references are only used to explain the differences and nuances between the various flavours described in this and related documents.

TOXICITY DATA ON UNBURNT MATERIAL

Health hazard data

The acute oral and dermal toxicity of chamomile oil is low. Oral administration of >5 g/kg to rats and mice or dermal application of 5 g/kg to the back of rabbits did not cause any lethality^[12]. Acute oral administration of chamomile oil (identity not specified) at 300-500 mg/kg had subtle effects on the behaviour of rats^[13]. Chamomile oil is non-irritating to the skin of humans or mice^{[14],[15],[16]}, but can cause mild irritation when applied to abraded rabbit skin^[12]. Chamomile oil may cause allergic contact dermatitis, particularly in persons with prior allergies to other *Compositae* plant pollens such as ragweed^[17]. Skin reactions have occurred after contact with the chamomile plants or chamomile-containing ointment; conjunctivitis developed in patients following eyewash with chamomile tea^{[18],[19]}. Individuals with known pollen allergies may be at greater risk for allergic reactions from consumption of chamomile teas. Severe allergic reactions have been seen in few individuals following consumption of chamomile tea^{[17],[20],[21],[22],[23],[24]}. Considering the high consumption of chamomile tea, the reported incidence of anaphylaxis is rare^{[25],[26]}.

In a genotoxicity study in mice, German chamomile oil did not induce sister chromatid exchanges in mouse bone^{[27],[28]}. No other genotoxicity studies of German chamomile oil were found in the published literature. In the Ames/*Salmonella* assay and *Bacillus subtilis* 'rec' assay, Roman chamomile oil was non-mutagenic^[29]. Several studies have shown that German chamomile oil has anti-mutagenic^{[30],[31],[32]} and anti-bacterial activity^{[33],[34],[35]}.

TOXICITY DATA ON BURNT MATERIAL

Data on the toxicity of chamomile flower oil, Hungarian as a cigarette ingredient has been evaluated in a series of studies. The results of these studies may be found in the following references:

Baker R.R. *et al.* 2004, "An overview of the effects of tobacco ingredients on smoke chemistry and toxicity", *Food and Chemical Toxicology*, 42S:53-83. **PEER REVIEWED**

Carmines E.L., 2002, "Evaluation of the Potential Effects of Ingredients Added to Cigarettes. Part I: Cigarette Design, Testing Approach and Review of Results," *Food and Chemical Toxicology*, 40:77-91. **PEER REVIEWED**

Rustemeier K. *et al.* 2002, "Evaluation of the Potential Effects of Ingredients Added to Cigarettes Part II. Chemical Smoke Composition," *Food and Chemical Toxicology*, 40:93-104. **PEER REVIEWED**

Roemer E. *et al.* 2002, "Evaluation of the Potential Effects of Flavor Ingredients Added to Cigarettes. Part 3. In Vitro Genotoxicity and Cytotoxicity," *Food and Chemical Toxicology*, 40:105-111. **PEER REVIEWED**

Vanscheeuwijck P.M. *et al.* 2002, "Toxicological Evaluation of Cigarettes without and with the Addition of Flavor Ingredients to the Tobacco. Part 4. Subchronic Inhalation Toxicity," *Food and Chemical Toxicology*, 40:113-131. **PEER REVIEWED**

Gaworski C.L. *et al.* 1998, "Toxicological evaluation of flavor ingredients added to cigarette tobacco: 13-week inhalation exposure in rats," *Inhalation Toxicology*, 10:357-381. **PEER REVIEWED**

Gaworski C.L. *et al.* 1999, "Toxicological evaluation of flavor ingredients added to cigarette tobacco: skin painting bioassay of cigarette smoke condensate in SENCAR mice," *Toxicology*, 139 1-17. **PEER REVIEWED**

CONCLUSION

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.

While Philip Morris International has not conducted human studies on the health effects of ingredients used in cigarette manufacture, studies have been conducted by Philip Morris International and/or others using scientifically accepted *in vitro* and *in vivo* toxicity assays with various ingredient mixtures. These studies show there is no meaningful difference in the composition or toxicity of smoke when the smoke from cigarettes with the added ingredient is compared to the smoke from cigarettes without this added ingredient. Based on a review of current published toxicological information, it is our scientific judgement that the addition of chamomile flower oil, Hungarian as an ingredient, at the levels used in our brands, does not increase the overall toxicity of tobacco smoke.

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