

**Evaluation of
Buchu leaves oil
for Use as a Cigarette Ingredient**

November 2005

INTRODUCTION

Buchu leaves oil (CAS # 68650-46-4) is used worldwide at levels up to **0.1 ppm** by Philip Morris International in roll your own and conventional cigarettes. This document is a review of the published toxicology information on buchu leaves oil abstracted from online toxicity databases.

TOXICITY DATA ON UNBURNED MATERIAL

The following information was generated from the MICROMEDEX database tool <http://csi.micromedex.com> on November 1st 2005, unless otherwise indicated.

Overview

Buchu leaves oil is obtained from the dried leaves of *Barosma betulina* or of *B. crenulata* or *B. seratifolia*, *Rutaceae*¹. Buchu leaf is used for inflammation and infection of the kidneys and urinary tract, for bladder irritations, as a disinfectant of the urinary tract, and as a diuretic. Buchu essential oil contains diosmin and pulegone which can cause irritation. There are no reports of cases of poisoning. The use of buchu leaves as an aroma or flavour corrigent in tea mixture is acceptable².

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 manufacturer's Association (FEMA), to be generally recognized as safe (GRAS) under current conditions of use.

TOXICITY DATA ON BURNT MATERIAL

Data on the toxicity of buchu leaves oil after combustion has been evaluated in a series of studies. The results of these studies may be found in the following references:

R.R. Baker 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**

E.L. Carmines, 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**

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

¹ The Merck index, an Encyclopedia of chemicals, drugs, and biologicals, eleventh edition, 1989

² The complete German Commission E Monographs, Therapeutic guide to herbal medicines, Blumenthal, 1998

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

These studies indicate that, at the levels tested, the chemicals used in the production of cigarettes do not increase the overall toxicity of cigarette smoke.

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.

While Philip Morris International has not conducted human studies on the health effects of ingredients used in cigarette manufacture, studies have been conducted using scientifically accepted in vitro and in vivo toxicity assays with various ingredient mixtures (see Toxicity Data on Burnt Material above). These studies show there is no meaningful difference in the composition or toxicity of smoke when the smoke from cigarettes with added ingredients is compared to the smoke from cigarettes without added ingredients. These findings are supported by similar studies from the published literature. It is our scientific judgment, based on the best available data, that buchu leaves oil used in our cigarettes does not increase the overall toxicity of cigarette smoke.