

Evaluation of
Anisyl Formate
For Use as a Cigarette Ingredient

April 2005

INTRODUCTION

Anisyl formate (CAS # 122-91-8) is currently used worldwide at levels below **1 ppm** in selected cigarette brands manufactured and/or distributed by Philip Morris International. This document is a review of current published toxicology information on anisyl formate abstracted from online toxicity databases.

TOXICITY DATA ON UN-BURNED MATERIAL

The following information was generated from the MICROMEDEX database tool <http://csi.micromedex.com> on April 28th 2005, unless otherwise indicated.

Overview

As a food flavouring additive, anisyl formate 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 recognized as safe (GRAS) under current conditions of use.

The Joint FAO/WHO Expert Committee on Food Additives has assessed anisyl formate as presenting no safety concerns at current levels of intake when used as a flavouring agent. The daily per capita intake is estimated at 0.4 µg/kg bw/day in the USA and at 0.8 µg/kg bw/day in Europe¹. It has also been defined as a flavouring substance which may be used as foodstuffs by the *Council of Europe Committee of Experts on Flavouring Substances* at an upper level of 15 mg/kg for foods.

Anisyl formate is a common cosmetic ingredient.

Anisyl alcohol – Salmonella typhimurium Ames test negative¹.

TOXICITY DATA ON BURNT MATERIAL

Data on the toxicity of anisyl formate as a cigarette ingredient has been evaluated in a series of studies.

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 3. In Vitro Genotoxicity and Cytotoxicity," *Food and Chemical Toxicology*, 40:105-111. **PEER REVIEWED**

¹ Safety evaluation of certain food additives and contaminants, WHO Food Additives Series 48: Hydroxy- and alkoxy-substituted benzyl derivatives. <http://www.inchem.org/documents/jecfa/jecmono/v48je15.htm>

P.M. Vanscheeuwijck 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**

These studies indicate that ingredients 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 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 judgement, based on the best available data, that anisyl formate used in our cigarettes does not increase the overall toxicity of cigarette smoke.