

**Evaluation of  
Beta-damascenone  
For Use as a Cigarette Ingredient**

**April 2005**

## **INTRODUCTION**

4-(2,6,6-trimethylcyclohexa-1,3-dienyl)but-2-en-4-one (CAS # 23696-85-7), also called beta-damascenone, is currently used worldwide at levels below **5 ppm** in selected cigarette brands manufactured and/or distributed by Philip Morris International. This document is a review of current published toxicology information on beta-damascenone 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 28<sup>th</sup> 2005, unless otherwise indicated.

### ***Overview***

Beta-damascenone is a naturally occurring member of the isoprenoids chemical family, which is present in a wide range of fruits. It is also present in the diet via alcoholic beverages such as beer and wine<sup>1</sup>, and is one of the major aromatic volatile components present naturally in tobacco leaves<sup>2</sup>.

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 *Joint FAO/WHO Expert Committee on Food Additives* (JECFA) has assessed beta-damascenone as presenting no safety concern at current levels of intake when used as a food flavouring agent. The daily *per capita* intake is estimated at 1µg/kg bw/day in Europe and at 0.08 µg/kg bw/day in the United States<sup>3</sup>.

Beta-damascenone is a common ingredient in cosmetic products. However, the International Fragrance Association (IFRA) has imposed restrictions of use on 1-Trimethylcyclohexenyl (cyclohexadienyl)-2-buten-1-ones (rose ketones), which include beta-damascenone, to an upper level of 0.02% in consumer products applied on skin, and of 0.2% in consumer products for which no skin contact is foreseeable under normal conditions of use<sup>4</sup>.

This material appears on the list of "Permitted Additives to Tobacco Products in the United Kingdom" (Department of Health, 2003) at a maximum level permitted for inclusion in finished cigarettes of 0.003% w/w tobacco.

---

<sup>1</sup> The Good Scents Company <http://www.thegoodscentscompany.com/> viewed on April 28<sup>th</sup> 2005

<sup>2</sup> Cai J. Liu B. Ling P. Su Q. Analysis of free and bound volatiles by gas chromatography and gas chromatography-mass spectrometry in uncased and cased tobaccos. *Journal of Chromatography A*. 947(2):267-75, 2002 Feb 22

<sup>3</sup> Safety Evaluation of Certain Food Additives and Contaminants, WHO Food Additives Series 42: Ionones and structurally related substances. The fifty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organization, Geneva 1999. Safety evaluation of certain food additives. IPCS INCHEM Home: <http://www.inchem.org/documents/jecfa/jecmono/v042je19.htm>

<sup>4</sup> The International Fragrance Company, Code and Standards: <http://www.ifraorg.org/GuideLines.asp/> viewed on May 4<sup>th</sup> 2005

Beta-damascenone has been reported to have an antispasmodic activity when isolated from a crude extract of the plant *Ipomoea pes-caprae*<sup>5</sup>.

The acute gavage LD50 for beta-damascenone in rats is >2000 mg/kg bw<sup>3</sup>.

## **TOXICITY DATA ON BURNT MATERIAL**

Data on the toxicity of beta-damascenone as a cigarette ingredient 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 3. In Vitro Genotoxicity and Cytotoxicity," Food and Chemical Toxicology, 40:105-111. \*\*PEER REVIEWED\*\*

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 judgment, based on the best available data, that beta-damascenone used in our cigarettes does not increase the overall toxicity of cigarette smoke.

---

<sup>5</sup> Pongprayoon U. Baeckstrom P. Jacobsson U. Lindstrom M. Bohlin L. Antispasmodic activity of beta-damascenone and E-phytol isolated from *Ipomoea pes-caprae*. *Planta Med.* 58 (1):19-21, 1992