

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

**June 2005**

## **INTRODUCTION**

Beta-damascone (CAS # 23726-92-3) 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 beta-damascone 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 June 10<sup>th</sup> 2005, unless otherwise indicated.

### ***Overview***

Beta-damascone is a C12 cyclic hydrocarbon that has a fruity odour.

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 recognized as safe (GRAS) under current conditions of use.

The Joint FAO/WHO Expert Committee on Food Additives has assessed beta-damascone as presenting no safety concerns at current levels of intake when used as a flavouring agent. The daily per capita intake is estimated at 0.2 µg/kg bw/day in the USA and at 0.7 µg/kg bw/day in Europe<sup>1</sup>. The E isomer (CAS # 23726-91-2) has 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 1 mg/kg for foods.

Beta-damascone is a common cosmetic ingredient.

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 cigarettes of 0.001 % w/w tobacco.

Male and female Wilster CF/Gif Carworth strain rats given beta-damascone in the diet at 2 mg/kg bodyweight for 90 days showed no significant changes. The NOEL could therefore be set at 2 mg/kg bw<sup>1</sup>.

The following information was generated from the RTECS – Registry of Toxic Effects of Chemical Substances, a database of MICROMEDEX Systems (<http://csi.micromedex.com>) on June 10<sup>th</sup> 2005. Health hazard data was only found for the E isomer.

### ***Health hazard data***

#### ***Acute toxicity***

LD50/LC50 - LETHAL DOSE/CONC 50% KILL

#### ***Rat***

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<sup>1</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), 1998. <http://www.inchem.org/documents/jecfa/jecmono/v042je19.htm>

LD50 - ROUTE: Oral; DOSE: 2920 mg/kg [Food and Cosmetics Toxicology. (London, UK) V.1-19, 1963-81. For publisher information, see FCTOD7. (13,487,1975)]

## **TOXICITY DATA ON BURNT MATERIAL**

Data on the toxicity of beta-damascone as a cigarette ingredient has been evaluated in the following study:

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\*\*

This study indicates 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 beta-damascone used in our cigarettes does not increase the overall toxicity of cigarette smoke.