

**Evaluation of  
Cocoa shell extract  
for Use as a Cigarette Ingredient**

**December 2005**

## **INTRODUCTION**

Cocoa shell extract (CAS # 8002-31-1) is currently used worldwide at levels below **100 ppm** in selected cigarette brands manufactured and/or distributed by Philip Morris International. This document is a review of the current published toxicology information on cocoa shell extract 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 December 8<sup>th</sup> 2005, unless otherwise indicated.

### ***Overview***

Cocoa shell extract is approved for use by the FDA as a natural extractive. The regulatory citation for cocoa shell extract is 21 CFR 182.20 – essential oils, oleoresins, and natural extractives that are generally recognized as safe for their intended use<sup>1</sup>.

Cocoa shell extract 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 5.0 % w/w tobacco.

The following information was generated from the REPROTOX – Reproductive Toxicology Center, a database of MICROMEDEX Systems (<http://csi.micromedex.com>) on December 8<sup>th</sup> 2005.

Cocoa butter (theobroma oil) is found in chocolate and is used as a base for suppositories and ointments. Like other tropical oils, cocoa butter is a rich source of cholesterol. One study has shown that the palmitic and stearic acids from cocoa butter in the diet are rapidly transferred into breast milk (1). We have been unable to locate additional references on possible reproductive or lactation effects of this agent.

## **TOXICITY DATA ON BURNT MATERIAL**

Data on the toxicity of cocoa shell extract as a cigarette ingredient has been evaluated in a series of studies. The results of these studies may be found in the following references:

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\*\***

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<sup>1</sup> Federal Register, 2004, "Code of Federal Regulations," Bonnie Fritts (ed.) US Government Printing Office, Washington, 21: 459.

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 the 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 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 judgement, based on the best available data, that cocoa shell extract used in our cigarettes does not increase the overall toxicity of cigarette smoke.