

**Evaluation of
Caraway oil
for Use as a Cigarette Ingredient**

November 2005

INTRODUCTION

Caraway oil (CAS # 8000-42-8) 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 current published toxicology information on caraway oil 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 November 1st 2005, unless otherwise indicated.

Overview

Caraway oil is obtained by steam distillation from the dried, crushed, ripe fruit of *Carvum carvi*¹. It is used primarily as a flavoring agent for food and alcoholic beverages, but also as a medicine to treat the irritable bowel syndrome in combination with peppermint oil². It has been shown to possess moderate antibacterial and antifungal properties. The volatile oil is composed mainly of carvone and limonene.

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.

Caraway oil 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 0.15 % w/w tobacco.

The following information was generated from the HSDB – Hazardous Substances Data Bank, a database of MICROMEDEX Systems (<http://csi.micromedex.com>) on November 1st 2005.

Non-Human Toxicity Excerpts

Caraway oil has been reported to exhibit antibacterial activities in vitro as well as larvicidal properties. It also has antispasmodic and antihistaminic activities on isolated animal organs. [Peer reviewed] [Leung, A.Y., Foster, S. Encyclopedia of Common Natural Ingredients Used in Food, Drugs, and Cosmetics. New York, NY. John Wiley & Sons, Inc. 1996., p. 120]

¹ <http://www.thegoodscentcompany.com/data/es1028851.html>, viewed on November 1, 2005.

² <http://myhealth.ucsd.edu/library/healthguide/en-us/Cam/topic.asp?hwid=hn-2060004>, viewed on November 1, 2005.

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 November 1st 2005.

Health hazard data

Acute toxicity

LD50/LC50 - LETHAL DOSE/CONC 50% KILL

Rat

LD50 - ROUTE: Oral; DOSE: 3500 mg/kg [Food and Cosmetics Toxicology. (London, UK) V.1-19, 1963-81. For publisher information, see FCTOD7. (11,1051,1973)]

Rabbit

LD50 - ROUTE: Skin; DOSE: 1780 mg/kg [Food and Cosmetics Toxicology. (London, UK) V.1-19, 1963-81. For publisher information, see FCTOD7. (11,1051,1973)]

Irritation

SKIN - STANDARD DRAIZE TEST

Rabbit

ROUTE: Skin; DOSE: 500 mg/24H; REACTION: Not Reported [Food and Cosmetics Toxicology. (London, UK) V.1-19, 1963-81. For publisher information, see FCTOD7. (11,1051,1973)]

Genetic effects

MUTATIONS IN MICROORGANISMS

Bacteria - S Typhimurium

DOSE: 5 ug/plate (+S9) [Kanagawa-ken Eisei Kenkyusho Kenkyu Hokoku. Bulletin of Kanagawa Prefectural Public Health Laboratories. (Kanagawa-ken Eisei Kenkyusho, 52-2, Nakao-cho, Asahi-ku, Yokohama 241, Japan) No.1- 1971- ((9),11,1979)]

TOXICITY DATA ON BURNT MATERIAL

Data on the toxicity of caraway oil 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 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 judgment, based on the best available data, that caraway oil used in our cigarettes does not increase the overall toxicity of cigarette smoke.