

**Evaluation of
Rose oil, bulgarian, true otto
for Use as a Cigarette Ingredient**

November 2006

INTRODUCTION

Rose oil (CAS # 8007-01-0) is currently used worldwide at levels up to **4.99 ppm** by Philip Morris International in selected roll your own or conventional cigarette brands manufactured and/or distributed by Philip Morris International. This document is a review of the published toxicology information on rose 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 2nd 2006, unless otherwise indicated.

Overview

Rose oil is used in tobacco, fruit, apricot, peach, raspberry, strawberry, plum, honey, and fruit punch. Bulgarian rose oil is one of the most valued (and expensive) of natural products. There is hardly a fruit flavor made that doesn't benefit from a trace of rose oil¹.

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 manufacturer's Association (FEMA), to be generally recognized as safe (GRAS) under current conditions of use.

Rose 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 RTECS – Registry of Toxic Effects of Chemical Substances, a database of MICROMEDEX Systems (<http://csi.micromedex.com>) on November 29th 2006.

Health hazard data

Acute toxicity

TDLO/TCLO - LOWEST PUBLISHED TOXIC DOSE/CONC

Mouse

TDLo - ROUTE: Intraperitoneal; DOSE: 400 mg/kg [Life Sciences. (Pergamon Press Inc., Maxwell House, Fairview Park, Elmsford, NY 10523) V.1-8, 1962-69; V.14- 1974-(72,91,2002)]

TOXIC EFFECTS:

Behavioral - Antianxiety

¹ Flavor Base "2004" Tobacco Edition, Leffingwell & Associates

LD50/LC50 - LETHAL DOSE/CONC 50% KILL

Rat

LD50 - ROUTE: Intraperitoneal; DOSE: 1045 mg/kg [MBI, Mediko Biologicheskaya Informatsiya. Medical-Biological Information. ('Ivana Vazova' No. 3, Sofia 1000, Bulgaria) 1967- ((3),8,1988)]

LD50 - ROUTE: Oral; DOSE: 2975 mg/kg [MBI, Mediko Biologicheskaya Informatsiya. Medical-Biological Information. ('Ivana Vazova' No. 3, Sofia 1000, Bulgaria) 1967- ((3),8,1988)]

TOXIC EFFECTS:

Sense Organs and Special Senses (Nose, Eye, Ear, and Taste) - Ptosis

Behavioral - Coma

Lung, Thorax, or Respiration - Cyanosis

Rabbit

LD50 - ROUTE: Skin; DOSE: 2500 mg/kg [Food and Cosmetics Toxicology. (London, UK) V.1-19, 1963-81. For publisher information, see FCTOD7. (12,979,1974)]

Irritation

SKIN - STANDARD DRAIZE TEST

Rabbit

ROUTE: Skin; DOSE: 500 mg/24H; REACTION: Mild [Food and Cosmetics Toxicology. (London, UK) V.1-19, 1963-81. For publisher information, see FCTOD7. (12,979,1974)]

Other multiple dose toxicity data

Rat

TDLo - ROUTE: Oral; DOSE: 12750 mg/kg/30D intermittent [MBI, Mediko Biologicheskaya Informatsiya. Medical-Biological Information. ('Ivana Vazova' No. 3, Sofia 1000, Bulgaria) 1967- ((3),8,1988)]

TOXIC EFFECTS:

Behavioral - Change in motor activity (specific assay)

Blood - Normocytic anemia

Liver - Other changes

TDLo - ROUTE: Oral; DOSE: 12750 mg/kg/6W intermittent [MBI, Mediko Biologicheskaya Informatsiya. Medical-Biological Information. ('Ivana Vazova' No. 3, Sofia 1000, Bulgaria) 1967- (3,8,1988)]

TOXIC EFFECTS:

Behavioral - Change in motor activity (specific assay)

Nutritional and Gross Metabolic - Weight loss or decreased weight gain

Others - Changes in testicular weight

TOXICITY DATA ON BURNT MATERIAL

Data on the toxicity of rose oil after combustion 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 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 rose oil used in our cigarettes does not increase the overall toxicity of cigarette smoke.