

**Evaluation of
Decanal
For Use as a Cigarette Ingredient**

June 2005

INTRODUCTION

Decanal (CAS # 112-31-2) 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 decanal 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 10th 2005, unless otherwise indicated.

Overview

Decanal is commonly used as a synthetic flavour or an adjuvant. It is a colourless liquid at room temperature and has a pleasant odour. It is a skin irritant of low toxicity.

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 decanal as presenting no safety concerns at current levels of intake when used as a flavouring agent. The daily per capita intake is estimated at 1.0 µg/kg bw/day in the USA and at 4.9 µg/kg bw/day in Europe¹. It has also 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 43 mg/kg for foods.

Decanal 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 June 10th 2005.

Non-Human Toxicity Excerpts

1. Decanal tested quant with *S. typhimurium* TA 98 & TA 100 and found not to be mutagenic. However, there was toxicity to the bacteria at about 3 µmol/plate. [PEER REVIEWED] [Florin I et al; Toxicology 15 (3): 219 (1980)]
2. The compound was tested externally on the eyes of rabbits, and, according to the degree of injury observed after 24 hours, rated on a scale of 1 to 10. The most severely injurious substances have been rated 10. 1-Decanal (mixed isomers) rated 1 on rabbit eyes. /1-Decanal (mixed isomers)/ [PEER REVIEWED] [Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 1028]

¹ Safety Evaluation of Certain Food Additives and Contaminants, WHO Food Additives Series 40: Saturated aliphatic acyclic linear primary alcohols, aldehydes, and acids. The forty-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 1998.
<http://www.inchem.org/documents/jecfa/jecmono/v040je10.htm>

The following information was generated from the RTECS – Registry of Toxic Effects of Chemical Substances, a database of MICROMEDEX Systems (<http://csi.micromedex.com>) June 10th 2005.

Health hazard data

Acute toxicity

LD50/LC50 - LETHAL DOSE/CONC 50% KILL

Rat

LD50 - ROUTE: Oral; DOSE: 3730 µL/kg [American Industrial Hygiene Association Journal. (AIHA, 475 Wolf Ledges Pkwy., Akron, OH 44311) V.19- 1958- (23,95,1962)]

Mouse

LD50 - ROUTE: Oral; DOSE: >41750 mg/kg [Food and Cosmetics Toxicology. (London, UK) V.1-19, 1963-81. For publisher information, see FCTOD7. (2,327,1964)]

TOXIC EFFECTS:

Behavioural - Excitement

Gastrointestinal - Hypermotility, diarrhoea

Skin and Appendages - Hair

Rabbit

LD50 - ROUTE: Skin; DOSE: 5040 µL/kg [American Industrial Hygiene Association Journal. (AIHA, 475 Wolf Ledges Pkwy., Akron, OH 44311) V.19- 1958- (23,95,1962)]

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. (11,1079,1973)]

SKIN - OPEN DRAIZE TEST

Rabbit

ROUTE: Skin; DOSE: 14.4 µg/24H ; REACTION: Severe [American Industrial Hygiene Association Journal. (AIHA, 475 Wolf Ledges Pkwy., Akron, OH 44311) V.19- 1958- (23,95,1962)]

Genetic effects

DNA REPAIR

Bacteria - B Subtilis

DOSE: 5 mg/disc [Osaka-shi Igakkai Zasshi. Journal of Osaka City Medical Association. (Osaka-shi Igakkai, c/o Osaka-shiritsu Daigaku Igakubu, 1-4-54 Asahi-cho, Abeno-ku, Osaka, 545, Japan) V.24- 1975- (34,267,1985)]

TOXICITY DATA ON BURNT MATERIAL

Data on the toxicity of decanal 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.

DATA ON THE EFFECTS ON HUMAN HEALTH

The following information was generated from the HSDB – Hazardous Substances Data Bank, a database of MICROMEDEX Systems (<http://csi.micromedex.com>) on June 10th 2005.

The low molecular weight aldehydes, the halogenated aliphatic aldehydes, and the unsaturated aldehydes are particularly irritating. The mucus membranes of the nasal and oral passages and the upper respiratory tract are affected, producing a burning sensation, an increased ventilation rate, bronchial constriction, choking, and coughing. The eyes tear, and a burning sensation is noted on the skin of the face. During low exposures, the initial discomfort may abate after 5 to 10 minutes but will recur if exposure is resumed after an interruption. /Aldehydes/ [**PEER REVIEWED**] [Clayton, G. D. and F. E. Clayton (eds.). Patty's Industrial Hygiene and Toxicology: Volume 2A, 2B, 2C: Toxicology. 3rd ed. New York: John Wiley Sons, 1981-1982., p. 2633]

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 decanal used in our cigarettes does not increase the overall toxicity of cigarette smoke.