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**Scientific Committee on Food**

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**Opinion**  
**of the Scientific Committee on Food**  
**on carnauba wax**

(expressed on 11 July 2001)

## Opinion of the Scientific Committee on Food on carnauba wax

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### Terms of reference

To review the safety of carnauba wax as a glazing agent in the light of the new information submitted following the Committee's request of additional information.

### Background

Carnauba wax is secreted from the leaves of the Brazilian fan palm *Copernicia cerifera*. Carnauba wax is used as glazing agent for confectionery including chocolate, small products of fine bakery wares coated with chocolate, snacks, nuts, coffee beans, dietary food supplements, fresh citrus fruits, melons, apples, pears, peaches and pineapples (1). No upper level is specified, but the Committee was previously informed that use levels are unlikely to exceed 200 mg/kg (2).

Carnauba wax was evaluated by SCF in 1990 when it was found to be temporarily acceptable as glazing agent (26<sup>th</sup> report) (2). The acceptance was made temporary pending supplementary toxicological data and technical data on use. In 1995, SCF reviewed additional data, which were still not found to be sufficient for a full acceptance and requested supplementary data on chromosome aberrations in mammalian cells *in vitro* and on the readiness of carnauba wax ester to hydrolyse (3). In 1993, JECFA allocated an ADI of 0-7 mg/kg bw based on the no-effect level from the combined reproduction and subchronic study, in which no adverse effects were observed up to the highest dose level tested of 1% in the diet (equivalent to 700 mg/ kg bw) (4).

Since then the Committee has received further data and these, together with the previous data, are reviewed below.

### Evaluation

#### Toxicology

Carnauba wax was not clastogenic in a new study (5) with cultured human lymphocytes, and it has formerly not been found mutagenic in three studies with *Salmonella typhimurium* test strains and in one study with *Saccharomyces cerevisiae* D<sub>4</sub> with or without metabolic activation (as cited in 4). In conclusion, carnauba wax is not genotoxic *in vitro*. There are no available long-term toxicity/carcinogenicity studies.

No treatment related adverse effects were observed in the new 90 day study with groups of 20 male and 20 female Fischer 344 rats (6). The rats were fed carnauba wax in the diet at doses of up to 1500 mg/kg bw daily for 90 days. In an extra group of 5 male and 5 female rats, the exposure was followed by a 90-day reversal phase. In addition, there was no evidence of tissue accumulation of

Carnauba wax. This finding was acceptable to the Committee instead of the requested hydrolysis data.

Carnauba wax has formerly been found to be without adverse effects in sub-acute studies with Wistar rats and Beagle dogs. In a 90-day study, a diet containing up to 10% carnauba wax was fed to groups of 15 male and 15 female Wistar rats, and no treatment related effects were observed (7). A diet containing up to 1.0% (w/w) carnauba wax was fed to groups of 6 male and 6 female dogs for 6 months and no treatment related effects were observed (8).

In a reproduction and subchronic feeding study 25 male and 25 female Wistar rats (F<sub>0</sub>) were fed 0, 0.1, 0.3, or 1.0% (w/w) of carnauba wax in the diet for 4 weeks prior to mating and throughout the remainder of the study including gestation and lactation (F<sub>0</sub>). Their progeny (F<sub>1</sub>) continued on the respective diets for 13 consecutive weeks after weaning. No treatment related adverse effects were recorded in this study (9).

In addition, no adverse effects were observed in a teratogenicity study in Wistar rats after dietary exposure to up to 1% carnauba wax (4).

### Exposure

Supplementary information on the usage levels of carnauba wax was in 1993 submitted to the European Commission (10). It was estimated that approx. 1,170 tonnes of food-grade carnauba wax is imported into the EU annually, but the European Wax Federation estimated that only about 100 tonnes are sold for food purposes and that the average intake per capita would be approximately 10 mg/day.

Carnauba wax is used in a limited range of chocolate and sugar confectionery products as a glazing agent. Based on the highest intake figures for chocolate and sugar confectionery in the EU, a total annual confectionery intake per capita would be 13.5 kg. Assuming as a worst case that all such products contain 200 mg/kg carnauba wax, the intake per capita from this source would be approximately 8 mg/day.

### **Conclusion**

Based on the available toxicological data and the exposure estimates of the substance from its permitted uses, the Committee withdraws the temporary status and accepts the use of carnauba wax as a glazing agent up to a maximum use level of 200 mg/kg of food.

### **References**

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7. Rowland, IR, Butterworth, KR, Gaunt, IF, Grasso, P and Gangolli, SD (1982). Short-term toxicity study of carnauba wax in rats. Food and Chemical Toxicology 20: 467-471 .
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