

INTERNATIONAL TECHNICAL CARAMEL ASSOCIATION

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Caramel Colors Safety Status February 2015

Caramel Colors have been used safely in food products since the 19th century. There are four different Classes (I, II, III and IV) of Caramel Colors that are appropriate for different applications. Caramel Colors are used in a wide range of food products, including but not limited to: soft drinks, beer, spirits, bakery products, cereals, sauces, soups, meats, spice blends, and related applications.

Caramel Colors are authorized to be used in food products globally. There have been questions raised recently, however, about a trace component, 4-methylimidazole (4-MEI), that is generated during manufacture of Class III and Class IV Caramel Colors. A U.S. National Toxicology Program (NTP) 2007 study reported lung tumors in mice fed very high levels of 4-MEI. In the same study, rats fed high levels of 4-MEI exhibited reductions in five types of tumors. California's Office of Environmental Health Hazard Assessment chose to list 4-MEI as a Proposition 65 chemical based solely on the reported results of the mouse study. This decision requires any product containing 4-MEI to have a warning label if the average daily dietary intake of 4-MEI from the food/beverage product exceeds 29 micrograms/day.

The safety of Caramel Colors has been established and reaffirmed numerous times over the last four decades. The European Food Safety Authority (EFSA), in a March 2011 opinion, reaffirmed the safety of all Caramel Colors, concluding that the combined intake of Caramel Colors for all consumer groups did not exceed the Acceptable Daily Intake. The U.S. Food and Drug Administration (FDA) has approved caramel as a color additive and has listed it as "*a generally recognized as safe*" food ingredient for decades. In November 2011, Health Canada said that 4-MEI, including that found in certain Caramel Colors, does "*not represent a risk*" to consumers. In November 2014, FDA stated that it does not have immediate or short-term concerns about the safety of Caramel Colors containing 4-MEI.

Regulatory specifications for Caramel Colors, including specifications for 4-MEI have been established by the Joint Expert Committee for Food Additives (JECFA), the European Union, FDA referencing the Food Chemicals Codex (FCC), and numerous other countries.

Caramel Colors continue to have global authorization from regulatory authorities for use in food and beverage products.

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