

CBA/2 and C57B1/6 mice. Groups of mice received diets containing either 17.2% beef tallow and 3.5% corn oil or 8.6% crude *Cuphea* oil and 3.5% corn oil. *Cuphea* oil is composed of 76% decanoic acid, 4.8% octanoic acid, 2.5% dodecanoic acid, 2.2% myristate, 3.4% palmitate, 0.7% stearate, 3.3% oleate, and 5.5% linoleate. Parental animals were fed for various times due to the short supply of *Cuphea* oil. C57B1/6 mice were fed for either 10 months, 8 months, or 5 months (F1, F2, and F3 generations), while the CBA/2 mice were fed for 11–12 months, 9–11 months, and 6–8 months (F1, F2, and F3 generations). Body weights, food intake, liver weights, and total serum cholesterol were analyzed as well as the number of pups born and surviving to weaning. Histopathology was performed on liver, left kidney, spleen, heart, lung, and one testis. The histopathology appears to have been done only on parental mice. Feeding of *Cuphea* oil containing decanoic acid to successive generations of two strains of mice had no effect on reproduction in either strain of mouse. In the F1 generation of the CBA/2 strain, the reported number of pups per female was decreased in the *Cuphea*-fed mice vs. the mice fed the basal diet without the *Cuphea* oil. However, this effect was not observed in any other generation of the CBA/2 strain or in any generation of the C57B1/6 strain and is therefore not interpreted as a treatment-related effect. Body weight in C57B1/6 and CBA/2 mice was reduced approximately 10% after 13 weeks of treatment but this effect was not observed in successive generations. Food intake was not consistently affected by treatment. Serum cholesterol was significantly increased in C57B1/6 mice after 3 months of treatment, and the increase was also observed after 5 and 12 months. Fatty vacuolization was observed in the liver of most mice after treatment. CBA/2 mice tended to accumulate fat as large vacuoles in periportal hepatocytes with smaller vacuoles in centrilobular hepatocytes. C57B1/6 mice had a more diffuse fatty change with large vacuoles in centrilobular areas.

#### E. Carcinogenicity/Mutagenicity

There are no published studies on carcinogenicity of decanoic acid, but available mutagenicity data indicate that decanoic acid is negative for mutagenic effects.

#### F. Physiological Effects

Decanoic acid was observed to enhance the permeability of the blood-brain in Wistar rats to several hydrophilic compounds when

administered into the carotid artery (Ohnishi *et al.*, J. Pharm. Pharmacol. 51: 1015–1018, 1998).

#### IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and drinking water (from ground water or surface water) and exposure through non-occupational pesticide use.

##### A. Dietary Exposure

1. *Food; existing tolerances and other clearances.* The Food and Drug Administration (FDA) has established a food additive clearance for decanoic acid at levels up to 234 ppm in sanitizing solutions (21 CFR 178.1010(c)(22), (30), (31), (34)), and has also cleared this chemical for direct addition to food for human consumption without limits.

Decanoic acid is also permitted for use in food as a lubricant, binder and as a defoaming agent as a component in the manufacture of other food-grade components, without limits, provided it meets the criteria as set forth in 21 CFR 172.860.

Worst case dietary exposures for the sanitizer use of decanoic acid have been calculated assuming that all food consumed by an adult or child has contacted a 4,000 cm<sup>2</sup> sanitized surface using decanoic acid, that a 1 milligram/centimeter (mg/cm)<sup>2</sup> sanitizer residue remains on the surface, and that 100% of the residue (28 ppm) is transferred to the food from the surface. Using these assumptions a worst case dietary exposure of 113 µg/day is calculated. For a 70 kg adult this becomes 1.6 µg/kg/day, and for a 15 kg child, intake is calculated as 7.5 µg/kg/day.

2. *Drinking water exposure.* The use of decanoic acid as a component of KX-6116 food surface sanitizer could result in the introduction of very low concentrations of decanoic acid into drinking water. However, this exposure through drinking water is expected to be minimal.

##### B. Non-Occupational Exposure

Based on the intended use of decanoic acid in food handling establishments, exposure to decanoic acid as a component of KX-6116 sanitizer through non-occupational sources is not likely to occur.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider available information

concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Based on the information discussed in Section VII below, EPA concluded that decanoic acid is sufficiently non-toxic that EPA can determine that it does not share a common mechanism of toxicity with other substances.

#### VI. Additional Safety Factor for the Protection of Infants and Children

Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

Based on the considerations discussed in Unit VII. of this document, EPA concluded that decanoic acid was sufficiently non-toxic that a margin of safety analysis was not appropriate. For the same reason, EPA has not applied an additional margin of safety for the protection of infants and children.

#### VII. Determination of Safety for U.S. Population, Infants and Children

Based on the following considerations, EPA concludes that decanoic acid is unlikely to pose a risk under all reasonable exposure scenarios:

1. The fatty acids as a group including decanoic acid have a safe history of use as natural components of many foods, as direct food additives, and as cosmetic ingredients. Furthermore, fatty acids are processed by known metabolic pathways within the body and contribute to normal physiological function.

2. The Joint FAO/WHO Expert Committee on Food Additives did not establish a specific allowable daily intake (ADI) for decanoic acid (i.e. Reference dose (RfD)) based on the knowledge that the compound is already a component of the human diet, has a long history of use, and does not present with any significant toxicology concerns and therefore does not represent a health hazard.

3. The Food and Drug Administration has established a food additive clearance for decanoic acid at levels up to 234 ppm in sanitizing solutions (21 CFR 178.1010(c)(22), (30), (31), (34)),