

a 15 kg child, exposure is calculated as 45 µg/kg/day.

2. *Drinking water exposure.* KX-6116 as a sanitizer contains pelargonic acid as its active component and low concentrations of pelargonic acid could be expected to be introduced into drinking water. However, exposure through drinking water is expected to be low and not of significance.

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

4. *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 Unit VII, EPA concluded that pelargonic acid is sufficiently non-toxic that EPA can determine that it does not share a common mechanism of toxicity with other substances.

F. Safety Factor for Infants and Children

Section 408 of the FFDCFA 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 III.G., EPA concluded that pelargonic 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.

G. Determination of Safety

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

1. Fatty acids such as pelargonic acid are processed by known metabolic pathways within the body and contribute to normal physiological function.

2. Pelargonic acid is naturally present at levels up to 224 parts per billion (ppb) in apples, 385 ppm in the skin of grapes, and 143 ppm in grape pulp. It is present in a number of other foods as well. An average serving of grapes containing 385 ppm of pelargonic acid in the grape skins would result in exposure to pelargonic acid to an average consumer of 164 µg/kg/day. In comparison, a worst case estimate of dietary exposure to pelargonic acid as a result of its use as sanitizer is 9.7 µg/kg/day for a 70 kg adult and 45 µg/kg/day for a 15 kg child.

3. The Food and Drug Administration has cleared pelargonic acid as a synthetic food flavoring agent (21 CFR 172.515), as an adjuvant, production aid and sanitizer to be used in contact with food (21 CFR 178.1010(b)) and in washing or to assist in lye peeling of fruits and vegetables (up to 1%) (21 CFR 173.315). Pelargonic acid is also exempt from the requirement of a tolerance when used in or on all food commodities, as a plant regulator on plants, seeds, or cuttings after harvest in accordance with Good Agricultural Practices (GAP). It is also exempt from a tolerance when used as a herbicide on all plant food commodities provided that allocations are not made directly to the food commodity except when used as a harvest aid or dessicant to any root or tuber vegetable, bulb, or cotton (40 CFR 180.1159).

4. Dietary toxicity testing evidenced adverse reactions only at doses that were at or above limit doses. Dermal toxicity testing showed no significant systemic reaction.

5. The estimated exposures to pelargonic acid and other fatty acids from direct or indirect addition to food as well as sanitizer uses are well below the doses administered in animal studies that are required to elicit an adverse effect. Accordingly, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to pelargonic acid.

IV. Other Considerations

A. Analytical Method(s)

Because an exemption from the requirement of a tolerance without numerical limitation for residues in food is being granted for pelargonic acid, an enforcement analytical method is not needed. However, an analytical method is available in cases of gross misuse. The analytical method is being made available to anyone interested in pesticide enforcement when requested, from Norm Cook, Antimicrobials

Division (7510C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Office location and telephone number: 1921 Jefferson Davis Highway, 3rd Floor, Arlington, VA 22202, (703) 308-8253.

B. Existing Tolerances

1. *40 CFR 180.1159.* Pelargonic acid is exempted from the requirement of a tolerance on all food commodities when used as a plant regulator on plants, seeds, or cuttings and all food commodities after harvest in accordance with GAP or as a herbicide when applications are not made directly to the food commodity except when used as a harvest aid or dessicant to: any root and tuber vegetables, bulb vegetable or cotton. When pelargonic acid is used as a harvest aid or dessicant, application must be made no later than 24 hours prior to harvest.

2. *21 CFR 178.1010(c)(37).* Pelargonic acid is permitted in food contact sanitizing solutions at a level up to 90 ppm.

3. *21 CFR 172.515.* Pelargonic acid may be safely used as synthetic food flavoring substances and adjuvants in food in the minimum quantity required to reproduce the intended effect.

4. *21 CFR 173.315.* Pelargonic acid may be used in an aliphatic acid mixture for washing or to assist in the peeling of fruits and vegetables. The aliphatic acid mixture may be used at a level not to exceed 1% in the lye peeling solution.

C. International Tolerances

No codex maximum residue levels have been established for the pelargonic acid.

V. Conclusion

An exemption from the requirement of a tolerance is established for residues of pelargonic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of pelargonic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of pelargonic acid up to 170 ppm per application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants. The sanitizer shall be applied by immersion, coarse spray, or circulation technique as appropriate to the equipment or utensil. No potable