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Geraniol; Exemption from the Requirement of a Tolerance
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ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
[OPP-2004-0068; FRL-7351-1]

Geraniol; Exemption from the Requirement of a Tolerance
AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the geraniol on all food commodity when applied/used to control Tetranychid mites. Natural Plant Protection S.A. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of geraniol.
DATES: This regulation is effective April 28, 2004

Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Geraniol is a monoterpene alcohol found in over 250 essential oils, and is widely used as a fragrance component in the manufacture of detergents, soaps, creams, lotions, cosmetics, and aromatherapy products. This chemical is also used as a synthetic flavoring agent in beverages, ice cream, and candies, and is generally regarded as safe (GRAS) under section 409 of the FFDCA (21 CFR 182.60). The toxicity studies submitted in support of this tolerance exemption are referenced below.

1. Acute oral toxicity (OPPTS 870.1100; 152-10; MRID 45262003).

Male and female Sprague-Dawley rats were tested with a single exposure to a pesticide product containing an active ingredient, geraniol, at 0.42% of the product. The pesticide was tested at doses ranging from 2,500 to 5,500 mg/kg of body weight and observed for 14 days. The oral LD for males and females were 5,242 mg/kg and 3573 mg/kg, respectively. Classification: Acceptable. Toxicity Category III, basedon the LD of female Sprague-Dawley rats. 50

2. Acute dermal toxicity (OPPTS 870.1200; 152-11; MRID 45262004).

Male and female New Zealand White rabbits were given 5,050 mg/kg of a pesticide product containing an active ingredient, geraniol, at 0.42%of the product, and observed for 14 days.
Classification: Acceptable.Toxicity Category: IV.

3. Acute inhalation toxicity (OPPTS 870.1300; 152-12; MRID45262005).

Male and female Sprague-Dawley rats were exposed for 4 hours to an atomospheric concentration of 2.64 mg/L of a pesticide product containing geraniol as an active ingredient and observed for 14 days.The acute inhalation LC was > 2.64 mg/L. Classification: 50 Acceptable. Toxicity Category: IV.

4. Primary eye irritation (OPPTS 870.2400; 152-13; MRID 45262006).

An acute eye irritation study was conducted in male and female albino New Zealand white rabbits using a a pesticide product containing an active ingredient, geraniol, at 0.42% of the product. The test substance was moderately irritating to the eyes of the test animals, causing corneal opacity (cloudiness) and conjunctivitis (redness) that cleared within 10 days following this exposure.

Classification:Acceptable. Toxicity: Category II.

5. Primary dermal irritation (OPPTS 870.2500; 152-14; MRID45262007).

The shaved skin of male and female New Zealand White rabbits was exposed to a single 0.5 mL dose of a pesticide product containing the active ingredient, geraniol, at 0.42% of the product for 4 hours and observed for 14 days for signs of skin irritation. The test substance was moderately irritating to the skin of the test animals, causing very slight to well-defined erythema (skin redness) that cleared within 14 days following exposure.

Classification: Acceptable.Toxicity Category: III.

6. Hypersensitivity (OPPTS 870.2500; 152-15; MRID 45262008).

The shaved skin of male and female Hartley guinea pigs was treated once weekly for 3 weeks with a pesticide product containing the active ingredient, geraniol, at 0.42% of the product. Skin redness (irritation) followed each treatment cleared within 48 hours. A challenge dose was given to an untreated site, and the animals observed for signs of allergic reaction (hypersensitiity) to the test material. The treated test and naive control animals showed no allergenicity (swelling, redness) at 24 and 48 hours after this challenge dose. The pesticide product was not a dermal sensitizer in Hartley guinea pigs. Classification: Acceptable. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. Food. Dietary exposure is expected to occur for most, if not all individuals to geraniol primarily from the consumption of fruits, beverages, food seasonings and its use as a flavoring agent/adjuvant in a wide variety of foods. The end-use product contains a low concentration of citronellol (0.42%) which is further reduced by dilution with water (no less than approximately 1:156 v/v) prior to application. Based on the extremely low application rate required to achieve the desired pesticidal effects, the Agency concluded that dietary exposure resulting from the proposed use on agricultural and greenhouse crops will be minimal and lower than levels of citronellol currently consumed in foods where it is naturally-occurring and/or present as a food additive.

2. Drinking water exposure. Geraniol residues in drinking water are expected to be minimal from its use as a pesticide. The pesticide product has a low use rate and the concentration of citronellol in the pesticide product is only 0.42%. The product is not intended for aquatic uses. Geraniol is insoluble in water and biodegrades rapidly in the soil, precluding its entry into ground and/or surface waters. Therefore, the Agency has concluded that it is highly unlikely that any residues resulting from the pesticidal use of citronellol would migrate into drinking water from natural sources.

B. Other Non-Occupational Exposure

1. Dermal exposure. Non-occupational dermal exposures to geraniol from its pesticidal use are expected to be minimal to non-existent. Human dermal exposures to geraniol occur primarily from its use as a fragrance in cosmetics, soaps, detergents, creams, and lotions, not from the agricultural use as a pesticide.

2. Inhalation exposure. Non-occupational inhalation exposures to geraniol from its pesticidal use are expected to be minimal to nonexistent. The main sources of human exposure to geraniol by this routeare from its use as a fragrance in cosmetics, soaps, detergents, creamsand lotions.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider the ``available information'' concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether geraniol has a common mechanism of toxicity with any other substances. It's mode of action is as a repellent, which is considered by the Agency as a non-toxic mode of action on target pest species. Further, geraniol does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purpose of this tolerance exemption action, EPA has not assumed that geraniol has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanisms of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

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

1. U.S. population. The Agency has determined that there is reasonable certainty that no harm will result from aggregate exposure to residues of geraniol to the U.S. population. This includes all anticipated dietary exposures and other exposures for which there is reliable information. The Agency arrived at this conclusion based on the anticipated low acute exposure estimates from its pesticidal use, the low mammalian toxicity of geraniol and the widespread use of geraniol in the human diet, cosmetics and fragrances found in a variety of food products and beverages, and that geraniol is considered GRAS under 21 CFR 172.515 as a synthetic flavoring and adjuvant permitted to be added directly to food for human consumption.

2. Infants and children. Section 408 of the FFDCA provides that EPA shall apply an additional ten fold margin of exposure for infants and children in the case of threshold effects. Margins of exposure are often referred to as uncertainty or safety factors, and are used to account for potential prenatal and postnatal toxicity and any lack of completeness of the data base based on available data and other information, EPA may determine that a different margin of exposure will be safe for infants and children or that a margin of exposure approach is not appropriate. Based on all the available information the Agency reviewed on geraniol, including a lack of threshold effects, the Agency concluded that geraniol is practically non-toxic to mammals, including infants and children. Since there are no effects of concern, the provision requiring an additional margin of safety does not apply.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide geraniol in or on all food commodities.

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