

tolerance, therefore, EPA has not assumed that eucalyptus oil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Aggregate Risks and Determination of Safety for U.S. Population, Infants and Children

The dietary exposure to residues of eucalyptus oil to the U.S. population from use of ApiLife Var is not likely to add significantly to current dietary exposure to eucalyptus oil. This is because no residues of eucalyptus oil were detectable (i.e., <0.01 ppm; measured as 1,8-cineole) when ApiLife was used in hives in the autumn in Europe for up to 5 years. Even if oil of eucalyptus residues were found in honey from hives treated with Apilife Var, they would have to be present at 5,000 times greater than the limit of detection to reach the level reported in ice cream (i.e., 50 mg/kg) and 170 times greater than the limit of detection to reach the level reported in non-alcoholic beverages (i.e., 1.7 mg/kg). Therefore, based on the long history of use of eucalyptus oil in the diet with no known adverse effect, coupled with the expectation of no to minimal residues from use of ApiLife Var in hives, it is reasonable to conclude that no harm will result from this pesticidal use. Accordingly, EPA finds that exempting eucalyptus oil from the requirement of a tolerance will be safe.

VI. Other Considerations

A. Analytical Enforcement Methodology

The Agency has not reviewed the method, nor its accuracy or reliability, used to previously analyze thymol and eucalyptus oil residues in honey; nor has it confirmed that prior use of ApiLife Var in European hives will give equivalent residues in hives in the United States. However, review of information submitted on a gas chromatographic method of analysis to measure thymol and eucalyptus oil in European hives, and the similarity of the European hives to U.S. hives allow for the conclusion that thymol and eucalyptus oil residues in honey from these hives will not be significantly greater, provided ApiLife Var is applied at the same rates to overwintering hives in the United States as was done previously in Europe.

The method may be requested from: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: madden.barbara@epa.gov.

B. International Residue Limits

No Codex Maximum Residue Levels (MRL) are established for thymol. However, Switzerland has established an MRL of 0.8 mg/kg, apparently not from a safety finding, but rather arising from legislation that prohibits foreign odors or tastes in honey. According to the World Health Organization, thymol residues in food are safe to consumers at up to 50 mg/kg. According to European Union regulation Nr. 2377/90, thymol is in group II of the non-toxic veterinary drugs which do not require a MRL. No Codex Maximum Residue Levels (MRL) are established for eucalyptus oil.

VII. Conclusion

Therefore, time-limited exemptions from the requirement of a tolerance are established for residues of thymol and eucalyptus oil in or on honey and honeycomb.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number

OPP-2003-0002 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 5, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.