



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 30 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: SACB Review of Waiver Requests for Product Chemistry/Identity and Acute Toxicology Data Requirements for the Registration of Cinnamon (HED Project No. 1-1782; I.D. No. 064714-R Roach Repel; DP Barcode: D166643)

TO: Phil Hutton/Mike Mendelsohn
Insecticide Rodenticide Branch (PM-18)
Registration Division (H7505C)

FROM: J. Thomas McClintock, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

JTM
12/27/91

THROUGH: Reto Engler, Ph.D.
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Reto Engler

ACTION REQUESTED: R.C.G. Inc. is seeking registration of Roach-Repel, a product containing cinnamon and [redacted] as active ingredients. Since cinnamon was recently classified by the OPP Biotechnology Workgroup as a biochemical pesticide the compound would be subject to the data requirements for biochemicals as outlined in 40 CFR 158.590. It should be noted that capsaicin which is the dried ripe fruit of various pepper plants was also classified as a biochemical pesticide by the Workgroup. On behalf of R.C.G. Inc., Chemical Consultants International Inc. has requested waivers for a portion of the Product Chemistry data requirements (e.g. 151B-17(d) through -17(f), 151B-17(h) through -17(j), 151B-17(m) through -17(p), and 63-10, -14, and -21) and for the acute battery of toxicology studies (152B-10 through -16). Waiver requests were not received for the remaining toxicology studies (152B-17 through -23) as outlined in 40 CFR 158.

BACKGROUND INFORMATION: The Product Manager is referred to previous memoranda (7 July 1991 memo from J. T. McClintock to P. Hutton/M. Mendelsohn and 26 November 1991 memo from J. T. McClintock to J. Ellenberger) for specific details.

DISCUSSION/CONCLUSION: Cinnamon is a naturally occurring plant constituent which has been used for centuries as a food additive and is considered GRAS according to FDA criteria. Although the OPP Biotechnology Workgroup recommended that the subject compound be classified as a biochemical pesticide the registrant has yet to respond to general deficiencies noted raised by SACB (see 7 July

INERT INGREDIENT INFORMATION IS NOT INCLUDED

1991 memorandum from J. T. McClintock to P. Hutton/M. Mendelsohn). For example, a thorough description of the harvesting procedure and the manufacturing process [REDACTED] to produce cinnamon was not addressed by the registrant. Of utmost importance and in view of the fact that waivers have been requested for specific acute toxicology data the registrant and/or manufacturer should ensure that the subject compound is of food-grade quality which should ensure that the product is devoid of hazardous components or materials.

SACB/HED would support the waiver requests for the specific Product Identity and Toxicology Data Requirements PROVIDED THAT the registrant submit the requested data/information as outline previously and reiterated above.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED