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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

21 April 1998

MEMORANDUM

SUBJECT: Review of Study: "Margin of Exposure Calculations - RBF5
EPA Reg. No. 64248-"

FROM: Mark I. Dow, Ph.D.
Insecticides Branch

TO: Susan T. Lewis, Branch Chief
Insecticides Branch
Registration Division 7505C

SUMMARY - The submission contains an estimate of dermal exposure of PCO's from using application devices to deliver a gel formulation to cracks/crevices. The resulting MOE is 243, 375. The submission also contains the results of a study to estimate the remotely possible and inadvertent oral exposure of children to a gel from a PCO, crack and crevice, application device. The resulting MOE is 152. The estimate of exposure of PCO's was done with techniques standard to the Program. The "children's" study is novel and seems to provide an adequate assessment of possible exposure.

DISCUSSION AND CONCLUSIONS - Per your request, I have reviewed the "Subject" submission which is authored by Dr. William C. McCormick (14 August 1997) of the Clorox Technical Center; Clorox Services Company. The submission contains an estimate of dermal exposure to a PCO from applying a crack and crevice gel product that contains 0.01% fipronil active ingredient. The study also contains an estimate of possible oral exposure to children in the rare event that a child might obtain access to a PCO gel application device. Since the application devices are limited to use by PCO's, it is not expected that children would have access to them.

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The estimate of exposure by a PCO was conducted with practices standard to OPP and is based upon information available in OPP and on assumptions. The NOAEL was identified by HED. The "dermal absorption factor" used in the submission is 4%. The dermal absorption factor cited by Health Effects Division is "<1%" (Personal communication, Dr. Jess Rowland (HED; 14 APR 98). One factor used in the estimate is not clear to me. That factor is ".01 skin contact" as noted in the equation on page V - Page 5 of 170. Study text states "Assuming an incidental contact of 1% RBF5...." Based on the formulation and methods of application and delivery, I have assumed that to indicate that only 1 per cent of the contacted material is believed to be "bioavailable." That is to say, that if a "drop" of toothpaste were placed on one's skin, only 1 per cent of the area of the drop would be "available" for contact and absorption. I am not able to confirm my supposition. In my opinion, if used properly, there should be very little contact with limited areas of the hand. Under the conditions listed in the submission, the daily MOE for PCO's is estimated to be 243,375. Even if the exposed surface area is doubled or tripled, the MOE would still be quite large. Further, the Agency's dermal absorption factor is less than 1/4 of that used in the submitted calculation.

The estimate of oral exposure to children is based on a study sponsored by Clorox and uses the same NOEL for acute neurotoxicity as noted by HED. In OPP, there have been estimates of oral exposure by children based on "volume of a swallow" of a liquid. The default is one teaspoonful, i.e., 5ml (Dr. Jerry Blondell/HED; personal communication; 7 April 1998). To my knowledge there have been no estimates of exposure to a gel product from the proposed types of application devices. The Clorox study included 68 children 42-51 months. First, the children were asked to take a sip of water from a small cup, as they might at home. The study showed that a "sip" of water from a small cup averaged 6.62 grams which is in agreement with the HED default. Then the children were introduced to a cheese spread which was used to simulate the gel in the application devices. The average amount of cheese spread taken from the various application devices, was 0.376g. The resulting MOE is calculated to be 152. The actual gel formulation contains a bittering agent. Therefore, it is assumed that a child would not ingest more than one "swallow."

Some interesting observations are that a number of the children would not participate in some portion of the study. For some children, obtaining cheese spread from the application devices had to be demonstrated. Due to these and factors briefly outlined above, and since the proposed delivery devices are only available to PCO's and not expected to be available to children, it would seem that any "risk factor" for the proposed delivery systems is negligible.

Dave Jaquith (personal communication, 16 APR 98, CEB-2/HED) reviewed the submission and concurred with the conclusions presented in this memorandum.

cc: D. Jaquith CEB-2/HED w study