10-15-76

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

Date: October 15, 1976

Subject: Killmaster II, EPA file symbol #26693-E
Application for new registration
Review of data submitted on 10/12/76 (resubmission)

From: Edwin R. Budd/Toxicology Branch

To: Frank Sanders/PM #12

Acc # 226836
Volatility study

RECOMMENDATION

Toxicology Branch has no objections to the new registration or the proposed uses of the subject product, Killmaster II, except as noted below:

(1) change label as directed in 5) below under "Label Change"
(2) submit toxicological data on petroleum distillates (listed on label as active ingredients) when EPA determines what these requirements will be.

BACKGROUND AND DISCUSSION

1) See earlier toxicology reviews on this application (dated 5/6/76, 5/25/76, and 8/12/76) and memoranda on conferences (dated 8/31/76 and 10/12/76).
2) The toxicity data referenced by the applicant for the active ingredient, chlorpyrifos (technical), is adequate and sufficient for the purpose of registration of the subject product. See toxicology review dated 8/12/76 for a summary of this data.
3) The toxicity data submitted by the applicant for the formulated product, Killmaster II, a "paint-on" formulation containing 2% chlorpyrifos, is adequate and sufficient for the purpose of registration of the subject product. See toxicology review dated 5/25/76 for a review of this data.
4) Additional toxicity studies on the formulated product were required in the toxicology review of 8/12/76. These studies were:
   (a) an acute inhalation LC-50 study
   (b) a 21 day subacute inhalation study
   (c) a 21 day subacute dermal study.

   In lieu of these studies, the applicant has submitted appropriate and adequate volatilization data establishing that toxicologically significant acute or subacute exposure will not occur by the inhalation route. See 6) below. The applicant has also made appropriate changes in the label which will significantly decrease the potential for subacute dermal exposure. In addition to the above, the applicant has referenced acute and subacute inhalation and dermal toxicity studies by Dow Chemical Company on the active ingredient,

chlorpyrifos. Based on this data and available information, the applicant has requested a waiver for the three studies described above. Toxicology Branch, after reviewing and evaluating this data and information, has found it to be acceptable and adequate for the purpose of waiving the requirements for these three tests and therefore recommends that the waiver requests be granted.

5) The newly revised label for this formulated product (submitted on 10/12/76) proposes the use of this product in non-food areas of food handling establishments. The application directions on the label are in accordance with PR Notice 74-6 (Residual Insecticides in Food Handling Establishments, 6/7/74) in all respects except the following (which should be corrected):

Label Change--Replace "Do not use in food areas of food handling establishments, restaurants or other areas where food is commercially prepared or processed." with "Do not use in food areas of food processing plants, restaurants or other areas where food is commercially prepared or processed."

6) Toxicology Branch recommends that a food additive regulation not be required for this proposed use in non-food areas of food handling establishments for the following reasons:

(a) volatilization data on the formulated product has been submitted (resubmission of 10/12/76) which establishs that toxicologically significant amounts of volatilized chlorpyrifos do not occur in closed unventilated rooms treated with Killmaster II when applied according to label directions for use. The highest measured air level of chlorpyrifos, in the study, was 9.5 ug/M^3. This represents a 21-fold reduction below the threshold limit value (TLV) for Dursban® (chlorpyrifos) set by the American Conference of Governmental Industrial Hygienists in 1973 (TLV = 200 ug/M^3).

(b) In the same study described above, data for a 0.5% spray formulation was collected and compared to that for Killmaster II. The highest measured air level of chlorpyrifos, for the 0.5% spray, was 18.0 ug/M^3--a level approximately double that of the Killmaster II formulation. A food additive regulation for 0.5% chlorpyrifos sprays is currently in effect for spot and/or crack and crevice treatments in food areas of food handling establishments (Federal Register, vol. 41, no. 27, February 9, 1976, pp 5631-2). The highest measured air level for Killmaster II was about one-half the highest measured level for the 0.5% spray.

(c) The proposed use of Killmaster II in food handling establishments is limited to use in non-food areas only. Based on the above studies, the potential for transfer of chlorpyrifos from non-food areas to food areas with subsequent contamination of foods with toxicologically significant amounts of chlorpyrifos is considered by Toxicology Branch to be nil.

7) Since EPA has not yet determined the toxicological data requirements for petroleum distillates as active ingredients and no data has been submitted or referenced on petroleum distillates by the applicant, these toxicological requirements are <u>not</u> yet satisfied for the purposes of registration of this product under Section 3 Regulations.

8) The use of this formulated product is classified as <u>restricted use</u>. As described in the Policy and Criteria Notice, number 2165.1 (October 6, 1976), the restricted use designation and statements should <u>not</u> appear on the label until October 21, 1977. The most recently submitted label (October 12, 1976), which does not contain a restricted use designation and statement, has been reviewed and found to be acceptable for the new registration of this product at this time.

Edwin R. Budd 10/15/76

For OEP 10/21/76