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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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SUBJECT: EPA No. 279-3055: Bifenthrin: Amended Registration to Reflect Changes in Manufacturing Process and Physical State of Technical Material. Access. No. 262950; RCB No. 1056

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TO: G. LaRocca / C. Dively, PM-15
Registration Division (TS-767c)

and

TOX Branch
Hazard Evaluation Division (TS-769)

The FMC Corporation, Philadelphia, PA, has submitted an application to amend the registration of its synthethic pyrethroid, bifenthrin, (previously known as biphenthrin). The amendment relates to an alternate manufacturing process that results in the formation of technical bifenthrin as a waxy solid rather than as a crystalline solid. The amendment also seeks to revise the label to declare a minimum of 89% active rather than 90%.

No permanent tolerances are established for bifenthrin, [2-methyl(1,1'-biphenyl)-3-yl]methyl 3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane carboxylate. Temporary tolerances have been established or proposed for a number of r.a.c.'s: cotton (5G3201), walnuts (5G3238), strawberries (5G3289), field corn (5G3235), peaches (6G3315), pears (6G3314), pecans (6G3313) and apples, (5G3202).

A product chemistry data package for bifenthrin was submitted by FMC and reviewed by RCB as part of PP#5G3201, (R. Loranger, memo of June 4, 1985). The current submission of product chemistry is similar to the previous submission, except for the description of the manufacturing process; changes, resulting from the altered manufacturing process, in the qualitative and quantitative profile of impurities occuring at levels greater than 0.1% from the analyses

of 5 current production runs; and a revised CSF reflecting this impurity profile.

The changes in the manufacturing process, in the profile of impurities, and in the CSF are given and discussed in the Confidential Appendix.

RCB has no concerns regarding the change in the physical state of the technical material from a crystalline solid to a waxy solid. Nor does RCB believe that this change or the changes in the impurity profile will affect residues. RCB defers to TOX as to the toxicological significance of the presence or increased levels of certain impurities. FMC states in its cover letter that the waxy solid form of technical bifenthrin rather than the recrystallized material was used for the previously submitted toxicological data base. We would point out that this laboratory or pilot plant material has a different impurity profile than that of the currently commercially produced material. We defer to TOX as to their concern as to the effect this may have upon the toxicological data base.

In its previous review of the product chemistry of bifenthrin, RCB expressed concern regarding the potential for the presence of chlorinated biphenyls in technical bifenthrin. As a result of this concern, RCB requested more detailed information, (chromatograms, validation data, etc.) to support the claim of the absence of such compounds at the 1 pppm level (R. Loranger, memo of June 4, 1985). The registrant has not specifically addressed this issue in the current submission, beyond repeating the statement that the Step 4 product, "has been examined for the presence of any unreacted mono- or dichlorobiphenyls; none have been detected at the 1 ppm level." We will require the experimental evidence for this assertion.

Conclusions

1. We consider that FMC has submitted a complete Product Chemistry data package for technical bifenthrin produced by a revised commercial manufacturing process. The data adequately meet all of the requirements of 40 CFR 158.120.

2. We conclude that the changes in the manufacturing process for technical bifenthrin that result in a change in the physical state and changes in the impurity profile pose no concern in regard to residues.

3. We defer to TOX as to the toxicological significance of the presence of additional impurities or increased levels of previously determined impurities.

4. RCB's previously expressed concern regarding the potential presence of chlorinated biphenyls in technical bifenthrin has not been addressed. We will require the experimental evidence, (chromatograms, validation data, etc.), for the assertion that such compounds are not present at the 1 ppm level.

Recommendation

We recommend that the product chemistry data for bifenthrin be accepted as meeting the product chemistry requirements for registration and for future petitions for tolerances provided the registrant supplies data regarding the absence of chlorinated biphenyls in bifenthrin and TOX is not concerned about the presence or increased levels of certain impurities.

Attachment: Confidential Appendix of 3 pages (cc to PP#5G3201, PM-15, TOX, S. F. R. F., Reviewer, and PMSD/ISB only.)

cc: Circ., S.F., PP#5G3201, R. F., Reviewer, PMSD/ISB
RDI:ARR:7/14/86:RDS:7/14/86
TS-769:JG:jg:RM:810:CM#2:7/14/85