FENVALERATE RCB REVIEW dated 7/10/85 pp 238-23

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

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA File No 201-URI. SS Pydrin® 1.9 EC. 3/28/85 Amendment. No Accession Number. RCB No 803.

FROM: Leung Cheng, Chemist L. Cheng
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THRU: Andrew Rathman, Section Head
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TO: Timothy Gardner, PM 17
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and

Toxicology Branch
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In our initial review (L. Cheng, memo of 11/26/84) on the subject registration, we recommended against the registration of SS Pydrin® 1.9 EC for several reasons. These are listed below.

Conclusion 1. [redacted] manufacturing steps has not been provided.

Conclusion 2. [redacted] inerts have not been furnished. Thus, we cannot determine whether they have been cleared under 40CFR§180.1001.

Shell has responded to the above two deficiencies. The identity [redacted]

A third deficiency is cited in Conclusion 5a of the 11/26/84 memo.

Conclusion 5a. In the present rat metabolism study, undegraded parent accounted for only ca 55% of fat residues when dosed with racemic fenvalerate, in sharp contrast to a previously reported study in which 90 or more percent of the fat residues was the parent (PP7F2013). Furthermore, when dosed with SS isomer-enriched

fenvalerate, only ca 15% of the fat residues was determined to be the parent. No additional identification of residues or explanation of discrepancies has been furnished. This will be required.

Shell's Response

Shell has submitted a report, MO-RIR-22-005-85, entitled "Characterization of ^{14}C-Residues in the Body Fat of Rats Following a Single Oral Dose of ^{14}C-SD 43775 and ^{14}C-SD 92459". Incomplete extraction was perceived to be the cause of these discrepancies.

RCB's Comment

This report is presumably the written form of what was presented on this issue in a meeting held earlier this year (memo of Conference, 3/14/85). SD 43775 denotes the racemic mixture and SD 92459 refers to the SS isomer-enriched fenvalerate.

In this report, a mixture of hexane and acetone (3:1) instead of just hexane was used for extraction. A larger sample size was also employed (5 grams of composite body fat tissues rather than 1 gram of inguinal fat). The hexane-acetone extracts were combined, suspended in 0.1 N citric acid buffer (pH 3) and the ^{14}C-residues were partitioned into chloroform. Greater than 99% of the activity in the fat tissues was extracted into the chloroform while the aqueous phase and the insoluble solid tissues contained negligible levels of radioactivity. The chloroform extracts after concentration were further partitioned against 1:1 hexane-acetonitrile to remove lipophilic coextractives. The acetonitrile phase which contained the ^{14}C-residues was concentrated. The residue thus obtained was placed on a silica gel plate and developed first with hexane followed by 25:25:1 hexane-acetone-acetic acid and 75:25:1 toluene-ether-acetic acid. Autoradiograms showed greater than 95% of the recovered activity was undegraded parent from all four treatment groups. The identity of fenvalerate was confirmed by GC.

We conclude undegraded parent is the residue of concern in the body fat of rats regardless of the isomeric ratio in the fenvalerate administered. The results agree with those from previous metabolism studies. This deficiency is resolved.

Conclusion and Recommendation

The deficiencies cited in our original memo have been resolved. We now recommend for the registration of SS Pydrin® 1.9 EC.

cc without Confidential Appendix: Circ
cc with Confidential Appendix: RF, Fenvalerate/Pydrin SF, Cheng, PM 17, TOX, Amended Use F, PMSD/ISB
RDI: ARRathman:7/10/85:RDSchmitt:7/10/85
TS-769:RCB:LCheng:CM#2:RM804:557-7484:7/10/85