

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2-5-96

Mr. Stuart McArthur
S. C. Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403

Dear Mr. McArthur:

Subject: Review of additional information
Raid Formula 278 Insect Killer
EPA Registration No. 4822-278
Your Submission dated March 13, 1995

The Agency has reviewed the additional information (1. Additional Data Relative to Air Sampling and Exposure for Raid Fumigator, 2) DOT Drop Test, Temperature Study & Sample Residue Analysis, 3) Dermal Sensitization Study of Permethrin Pellets in Guinea Pigs- Closed Patch Technique (MRID 43581801), and 4) Acute Dermal Toxicity Study of Permethrin Pellets in Rabbits Calcium Oxide Leakage/Exposure (MRID 43581802) provided by you in response to our letter dated February 24, 1994 and reached the following conclusion:

1. The Agency's previous concerns have been adequately addressed and no further information regarding these studies is required.

A copy of the review is enclosed for your information.

Sincerely yours,

George T. LaRocca
Product Manager (13)

CONCURRENCE

Insecticide-Rodenticide Branch
Registration Division (7503C)

SYMBOL	7503C						
SURNAME	PAO						
DATE	2/5/96						



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

JUN 20 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Additional Information Provided on a Raid 278 Permethrin
Fumigator

TO: George LaRocca, Product Manager Team 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: Kathleen Martin, Chemist *Kathleen Martin*
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

THROUGH: Mark Dow, Ph.D., Section Head *Mark Dow*
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Larry Dorsey, Chief *Larry Dorsey*
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find below the OREB review of:

DP Barcode	D214172
Pesticide Chemical Code	109701
EPA Reg. No.	4822-274 and 4822-278
PHED?	No

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I. INTRODUCTION

In November 1993 OREB reviewed studies submitted by S.C. Johnson (S.C.J.) on exposure resulting from smoke-fumigation using Raid Formula 278 Insect Killer; permethrin is the active ingredient (see memorandum from Arthur O. Schlosser to George LaRocca, November 9, 1993). In February 1994 the Registration Division sent S.C. Johnson a letter listing, among other things, the deficiencies with their studies (see letter from George T. LaRocca to Stuart McArthur, February 24, 1994). Please note that EPA reviewed a protocol for the exposure study in February 1988 (see letter from George T. LaRocca to Robert Yocum, February 3, 1988); the review stated that if the indicated changes were included in the study protocol, it would be acceptable.

Listed below are the deficiencies and additional data that the Agency requested in the February 1994 letter:

Calcium Oxide Leakage and Exposure

"To address the accessibility of calcium oxide to adults (and evidence of.... powder inside the package) we suggest you conduct an additional drop test similar to the Department of Transportation 4 foot drop test procedures to hazardous material to ascertain if any material is being released. A sufficient number (15) of containers should be examined/analyzed for any residue. The identity and amount of residue should be determined. If calcium oxide is being released additional toxicity and exposure data may be required."

Air Sampling and Exposure Study

"The study submitted was found unacceptable due to several deficiencies. A new study is required in accordance with EPA Guidelines unless the deficiencies can be addressed.

1. The report did not include estimations of expected inhalation or dermal exposure to persons who may occupy the treated areas after the ventilation period.
2. Surface transfer coefficients were not developed.
3. Samples were not taken beyond the 3.5 hour activation period.
4. The method sensitivity for air sampling was about five times higher than recommended by EPA Guidelines.

5. There was a deficiency in the number of replications reported and in the supporting quality control information required by the Subdivision U Guidelines.
6. Since permethrin is classified as a Class C Carcinogen, estimation of repeated product use is needed to complete a cancer risk assessment."

II. DISCUSSION

S.C.J. has recently submitted data to address these concerns. The following provides OREB's analysis.

Calcium Oxide Leakage and Exposure

S.C.J. sampled the outside of 15 metal cartridges and detected no calcium oxide or calcium hydroxide. They also drop-tested 24 units -- 12 from a height of 3 feet and another 12 from a height of 5 feet. Further, another 30 units (15 activated and 15 non-activated) were drop-tested from a height of 6.75 feet. No breakage was found in any of the tests and no evidence of powder, particles, or debris was detected. OREB believes that exposure to calcium oxide will be minimal. Thus, no further calcium oxide exposure data will be required.

Air Sampling and Exposure Study

See Table 1 (Discussion of the Air Sampling and Exposure Study) for a comparative summary of EPA's previous concerns, S.C.J.'s submission, and OREB's comments on the latest S.C.J. submission.

III. CONCLUSION

OREB has reconsidered the additional information that has been submitted by S.C.J. and believes that the previous concerns have been adequately addressed. Therefore, no further information regarding these studies is required.

TABLE 1. Discussion of the Air Sampling and Exposure Study

EPA'S FEBRUARY 1994 COMMENTS	S.C. JOHNSON'S 1995 RESPONSES	OREB'S JUNE 1995 CONCLUSIONS
1. No Inhalation or Dermal Exposure Estimates	S.C.J. states that human exposure data are not needed because no airborne residues remained in the treated areas after the ventilation period. To prove the point that human exposure is not a problem, they provided epidemiological data showing that there were no reported exposures that resulted in a major medical outcome.	OREB estimated the dermal and inhalation exposure in the 1993 review. No further dermal or inhalation information will be required; S.C.J. has provided sufficient information to show that the material has dissipated by 3.5 hours.
2. No Surface Transfer Coefficients	S.C.J. cited the Ross, 1990 study for the transfer coefficients.	No further information is required.
3. No Samples Taken Beyond 3.5 Hours	S.C.J. states that sampling beyond 3.5 hours was unnecessary because of the absolute lack of any detectable permethrin after 3.5 hours.	EPA agrees that no further sampling should be required.
4. Inadequate Method Sensitivity	S.C.J. argues that the study was conducted according to EPA-approved protocol and that it is inappropriate for the Agency to comment on inadequate method sensitivity 'after the fact.'	In the February 1988 protocol review, EPA states that strict quality assurance procedures must be followed and indicated that the Subdivision U Guidelines should be used. It appears that the sensitivity for air sampling (0.04 µg/L) is reasonable. Therefore, no further information is needed.

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EPA'S FEBRUARY 1994 COMMENTS	S.C. JOHNSON'S 1995 RESPONSES	OREB'S JUNE 1995 CONCLUSIONS
5. Deficiency in Number of Replicates	S.C.J. stated that in the protocol neither they nor the Agency specified the number of samples that had to be taken. Therefore, S.C.J. questions EPA's comment that "there was a deficiency in the number of replications reported."	According to EPA's 1988 protocol review, S.C.J. had not specified the number of replicates in the protocol outline. EPA commented that enough replicates should be included to allow a reliable estimate of the expected variability of exposure that would result from use of the product. EPA has reconsidered S.C.J.'s exposure study and believes that the number of replicates provided in the study is adequate to assess exposure.
6. Repeated Use Information is Needed	S.C.J. believes that permethrin has a low carcinogenic potential. They cite a 1982 conclusion of Doug Camp. However, S.C.J. did state that Art Schlosser's assumption of 4 uses a year is an accurate estimate of repeat product use.	EPA now classifies permethrin as a Group C carcinogen (possible human carcinogen). SOURCE: Memorandum from Tina Manville to James Stone, March 6, 1995. Thus, the exposure and risk assessments will be carried-out accordingly. However, no further use information is required.

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REFERENCES

Ross J, et.al. 1990. "Measuring Potential Dermal Transfer of Surface Pesticide Residue Generated from Indoor Fogger Use: An Interim Report." *Chemosphere* 20 (3-4): 349-360.

U.S. EPA. 1988. Review from Michael Firestone to George LaRocca. Protocol Review for Exposure Study. January 13, 1988.

U.S. EPA. 1988. Letter from George T. LaRocca to Robert V. Yocum. "Proposed Test Protocol for Exposure Study." February 3, 1988.

U.S. EPA. 1993. Memorandum from Arthur O. Schlosser to George LaRocca. "Review of Exposure Assessment for Room Fumigation, and Product Container Leakage and Activation Studies for Permethrin Fumigators," November 9, 1993.

U.S. EPA. 1994. Letter from George T. LaRocca to Stuart McArthur. "Follow-Up to Calcium Oxide Exposure....," February 24, 1994.

U.S. EPA. 1995. Memorandum from Tina Manville to James Stone. "Exposure Assessment for AEH-920 Aqueous Insecticide & Fungicide...", March 6, 1995.

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