UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 1 4 1986

MEMORANDUM

SUBJECT: Theoretical Margins of Safety for lindane exposure:
           Recalculation to include both dermal and inhalation
           exposure for specified uses.

                                          TOX CHEM No. 527.

FROM: John Doherty   7/23/1986
           Toxicology Branch
           Hazard Evaluation Division (TS-769)

TO: Amy Rispin
           Chief
           Science Integration Staff
           Hazard Evaluation Division (TS-769)

THRU: Edwin Budd
           Section Head
           Toxicology Branch
           Hazard Evaluation Division (TS-769)

THRU: William Burnam
           Deputy Branch Chief
           Toxicology Branch
           Hazard Evaluation Division (TS-769)

       In a previous memo from Toxicology Branch (TB), Margins
of Safety (MOSs) for certain uses of lindane were calculated
based on inhalation exposure (refer to J. Doherty memo dated
June 24, 1986 for EPA ID. No. 009001 addressed to C. Langley).
In an interdivisional meeting held on July 9, 1986, it was
decided that additional calculations of the MOSs for these same
uses would be desirable. The revised calculations should
include dermal as well as inhalation exposure. As per in-
structions from Amy Rispin, the dermal exposure information
provided by Kyle Barbehenn (memo dated September 18, 1985
attached) should be used.

Inspection of the data tables provided by Dr. Barbehenn reveal that there is no dermal exposure listed for ~~the~~ four of the five uses of lindane for which MOSs were calculated in the original June 24, 1986 memo. For example there is no human dermal exposure for the <u>flea collar</u>, <u>shelf paper</u> or <u>hardwood treatment</u> uses of lindane. The fourth use for which a MOS was calculated was for <u>moth treatment by "employees"</u> based on 225 days/year exposure. No human dermal exposure is listed in the Barbehenn memo for this use. Dermal exposure is listed, however, for <u>moth treatment applicators</u> with 26 days per year exposure. The exposure in this case is not likely to be continuous for 26 days. In the June 24, 1986 memo, it was decided, however, that the use of the 90 day inhalation study was inapplicable for exposures of less than 90 days because there was no evidence that lindane exposure for shorter periods such as 26 days per year (not continuous exposure) results in kidney effects.

As per discussion with Dr. Barbehenn on July 22, 1986, it was decided that the fifth use of lindane (that of the <u>forestry application</u>) would be used as a <u>model</u> for estimating a MOS for lindane use where the combined inhalation and dermal exposures are incorporated. It should be noted that this is a <u>model</u> system only and represents a combined worst case exposure.

Total exposure:

$$\begin{array}{lll} \text{respiratory} & = & 1.8 \times 10^{-3} \text{ mg/kg/day} \\ \text{dermal} & = & \underline{25.0 \times 10^{-3} \text{ mg/kg/day}}* \\ & & 26.8 \times 10^{-3} \text{ mg/kg/day} \end{array}$$

MOS = [NOEL from the inhalation study]/[Total Exposure]

" = $[10.6 \times 10^{-3}$ mg/kg/day]/$[26.8 \times 10^{-3}$ mg/kg/day]

" = 0.396

A MOS of <u>less than 1</u> results. This MOS was arrived at essentially by relating <u>dermal</u> exposure to a NOEL derived from an <u>inhalation</u> study. TB expresses the reservation that determining a theoretical MOS by combining dermal exposure with an inhalation NOEL would likely overestimate the MOS by giving a lower numerical value and implying a greater hazard than exists. A better estimate of the MOS resulting from dermal exposure would be made by incorporating the NOEL from a dermal toxicity

*The dermal exposure of 25×10^{-3} mg/kg/day was derived from Dr. Barbehenn's table which indicated an exposure of 0.25 mg/kg/day. This was multiplied by 0.1 to adjust for 10% absorption to give the amount of lindane theoretically absorbed from this use.

study. TB again notes that the forestry application use is for 30 days/year (not continuous) whereas the inhalation study was a 90 day (continuous exposure) study which is not considered by TB to be applicable for the purposes of determining a MOS for this use. Using the NOEL from the study with the continuous exposure period would again result in overestimating the MOS.

Lastly, using the model equation as above, a theoretical MOS for the "moth spray applicators" can be calculated to be 51.5 as follows:

$$\text{Respiratory Exposure} = 2.6 \times 10^{-5} \text{ mg/kg/day}$$
$$\text{Dermal Exposure} = 18.0 \times 10^{-5} \text{ mg/kg/day}$$
$$\text{Total} = 20.6 \times 10^{-5} \text{ mg/kg/day}$$

$$\text{MOS} = [10.6 \times 10^{-3} \text{ mg/kg/day}]/[20.6 \times 10^{-5} \text{mg/kg/day}]$$

$$= 51.5$$

This MOS is also considered to be an overestimation because the exposure is not continuous and a dermal toxicity study was not used in combination with dermal exposure. Note also that this MOS number is higher than the MOS of 35.3 which was calculated for inhalation exposure to "employees", a different subset of workers for the moth-treatment use of lindane.

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