



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 11 0 11

SUBJECT: PP #1E2473 - HCB residues in mint oil; TOX response to RCB
deferral of 4/10/81, K. Arne

FROM: David Ritter, Toxicologist
Review Section #1
Toxicology Branch/HED (TS-769)

TO: E. Gross, Minor Uses Officer
Registration Division (TS-767)

THRU: William Burnam, Deputy Chief
Toxicology Branch/HED (TS-769)

Introduction:

RCB (review of K. Arne, 4/10/81) defers to TOX as to our concern for potential residues of hexachlorobenzene (HCB) at levels calculated at up to 0.1 ppm in mint oil, resulting from the use of chlorothalonil (Daconil; of which HCB is contaminant) in mint hay. There is no expectation of residues of Daconil per se in mint oil from the proposed use.

TOX originally supported the proposed tolerance of 0.1 ppm daconil in mint and in mint hay in our review of 3/23/81, D. Ritter. We deferred to RCB as to residues in mint oil and the flesh, eggs and milk of livestock being fed such residue-bearing animal feeds.

RCB has in this review concluded that a label restriction prohibiting the feeding of fresh or mint hay would preclude residues in these human feed items.

7-8-81
RCB
DUTCH
Arne
Filipetich

215B

042 7/8/81

11/14/81

mt
7/14/81

Conclusions:

1. We expect no appreciable increase in oncogenic risk due to estimated potential residues of HCB in mint oil at calculated levels up to 0.1 ppm.
2. Our concern for residues in milk, eggs and livestock flesh for potential residues of HCB resulting from the proposed use is alleviated by reason of the label feeding restriction.

Detailed Considerations:

1. Oncogenic Risk Analysis

- a. For the purpose of this Analysis we are considering that the Food additive(s) Spearmint oil and Peppermint oils constitute no more than 0.03% of the total human dietary. They are GRAS pursuant to 21 CFR 172.10 (Direct Food Additives).
- b. Maximum calculated residues of HCB resulting from the use of Daconil in mint is 0.1 ppm (Arne review of 4/10/81).

2. Interpretation:

$$0.1 \text{ ppm HCB} \times 0.03\% \text{ diet} = 10^{-7} \times 3 \times 10^{-4} = 3 \times 10^{-10} \text{ ppm.}$$

This value falls well within the R. Gardner Upper limit on Risk (one-hit) Analysis for oncogenic Risk of 1/10/80 in association with Daconil and the NCI report # NCI 66TR-41, and Cabral, et al, 1977. For HCB, the one-hit model Upper limit on Risk is ca 8×10^{-5} .

This level is of no regulatory significance for oncogenic potential as delineated in the Nitrosamine Policy document, FR 45:124, 6/24/80; it falls well within the level of 10^{-6} as described in that document.

TS-769:RITTER:slv:CM#2:RM.816:X73710:7/7/81 card 2