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

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AUG 26 1996

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: REVISED Propazine Qualitative Risk Assessment Based On 1995 Re-Read of Female Mammary Gland Slides From 1981 Sprague-Dawley Rat Dietary Study

P.C. Code 080808

TO: William Dykstra, Toxicologist
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Pursuant to the discussion at the Propazine Carcinogenicity Peer Review Committee meeting of August 28, 1996, EPA's consulting pathologist, Dr. Lucas Brennecke, recommends that mammary gland fibroadenomas should not be combined with mammary gland adenomas and carcinomas. This decision is reflected in this revised qualitative risk assessment.

Background

A chronic oral toxicity study with Propazine in Sprague-Dawley rats was conducted by International Research and Development Corporation, Mattawan, Michigan, for Ciba-Geigy Corporation, Agricultural Division, Greensboro, North Carolina, and issued April 18, 1981 (IRDC Study No. 382-007; MRID No. 000414-08).

The study design allocated groups of 60 rats per sex to dose levels of 0, 3, 100, or 1000 ppm of Propazine for 105 weeks. An additional 5 rats per sex in the control and high dose groups were designated for interim sacrifice at week 53.

Table 1. Propazine - Sprague-Dawley Rat Study

Female Mortality Rates[+] and Cox or Generalized K/W Test Results

Dose (ppm)	Weeks 1-26	27-52	53[i]	53-78	79-105[f]	Total
0	1/64[a]	2/62[b]	4/60	8/58	12/50	23/59 (39)**
3	0/60	2/60	0/58	3/58	18/55	23/60 (38)
100	1/60	0/59	0/59	1/59	14/58	16/60 (27)
1000	3/63[c]	0/60	5/60	6/55	24/49	33/58 (57)

[+]Number of animals that died during interval/Number of animals alive at the beginning of the interval.

[i]Interim sacrifice at week 53.

[f]Final sacrifice at week 105.

[a]One accidental death at week 13, dose 0 ppm.

[b]One accidental death at week 52, dose 0 ppm.

[c]Two accidental deaths at week 13, dose 1000 ppm.

( )Percent.

Note: Time intervals were selected for display purposes only.

Significance of trend denoted at control.

Significance of pair-wise comparison with control denoted at dose level.

If *, then $p < 0.05$. If **, then $p < 0.01$.

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