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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Baygon - Rat Study - Qualitative and Quantitative Risk Assessment

Caswell No.: 508

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Summary

The potency estimate, Q_1^* of Baygon is 7.9×10^{-3} $(mg/kg/day)^{-1}$ in human equivalents $[B_2]$. This estimate is based upon the geometric mean of male and female bladder tumors (carcinomas and papillomas) in rats.

Background

Data from a 2-year dietary study in SPF rats (Bayer Report No. 9954) were statistically evaluated and presented to the Peer Review Committee on June 26, 1986.

On the basis of all available evidence, the committee classified Baygon as a [B_2] carcinogen.

Data Analysis

Survival was not significantly reduced in either sex in this species of animals with increasing doses of Baygon. This statistical outcome was based upon the application of the D.G. Thomas, H. Breslow, and J.J. Gart computer program. See Table 1 for tabular results. The survival tables are broken into aggregate time intervals for display purposes only.

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Table 1. Baygon - Rats, Mortality Rates[+]

A. Males

Dose (ppm)	Weeks 0-51	52[a]- 78	79-107	108-110	Total[a]
0	2/60	1/48	9/47	1/38	13/50 (26)
200	0/60	1/50	5/49	0/44	6/50 (12)
1000	1/60	1/49	6/48	1/42	9/50 (18)
5000	2/60	0/48	12/48	0/36	14/50 (28)

B. Females

Dose (ppm)	Weeks 0-51	52[a]-78	79-107	108-110	Total[a]
0	1/60	3/49	8/46	0/38	12/50 (24)
200	0/60	2/50	6/48	2/42	10/50 (20)
1000	1/60	2/49	7/47	0/40	10/50 (20)
5000	0/60	3/50	10/47	1/37	14/50 (28)

[+]Number of Animals that Died/Total Number of Live Animals at Beginning of Week
[a]/ excluded Interim Sacrifice of 10 animals
( ) percent.

At the suggestion of Byron Backus (Reviewer), bladder tumors (carcinomas and papillomas), the most frequent type found in both sexes, were analyzed both combined and separately, for carcinomas and papillomas, per sex. All three tumor type trends, evaluated by means of the Cochran-Armitage Trend test (because of the lack of any significant survival problem), indicated very significant ($p < .001$) increases in the rates in both sexes with increasing doses of Baygon. In addition, the pairwise comparisons of controls with the high dose group in both sexes, by use of the Fisher's Exact test, also resulted in significant ($p < .01$) increases in total bladder tumors. See Table 2 for details.

Table 2. Baygon - Rat Study, Bladder Tumor Rates[+] and Cochran-Armitage Trend Test and Fisher's Exact Test Results

A. All Bladder Tumor Rates[+]

Dose (ppm)	Males	Females
0	0/58**	0/48**
200	0/60	0/46
1000	1/59	0/48
5000	34/57**	33/48**

B. Carcinomas only - Rates[+]

Dose (ppm)	Males	Females
0	0/58**	0/48**
200	0/60	0/46
1000	0/59	0/48
5000	8/57**	5/48*

C. Papillomas only - Rates[+]

Dose (ppm)	Males	Females
0	0/58**	0/48**
200	0/60	0/46
1000	1/59	0/48
5000	26/57**	28/48*

[+]Tumor Bearing Animals/Number of Animals Examined.
Note - Significance of Trend Analysis denoted at Control; significance of pairwise comparison with control denoted at Dose level.
*$p < .05$
**$p < .01$

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Dose-Response Review

Since mortality in the rat study was not significantly impaired with increasing doses of Baygon, the potency estimate, Q_1^* of the chemical was obtained through the use of K. Crump's Multi-Stage Model computer program. The resulting potency estimates in parts per million of Baygon were converted to mg/kg/day for animals by using Lehman's Tables and then to human equivalents by use of the interspecies surface area adjustment as recommended by EPA Cancer Guidelines.

The resultant potency estimates were as follows:

	Q_1^* (mg/kg/day)$^{-1}$
Rat	Animal (mg/kg/day)$^{-1}$
Male	8.9×10^{-4}
Female	4.9×10^{-4}
Geometric Mean	6.6×10^{-4}
In Human Equivalents	7.9×10^{-3}