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

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AUG 2 1994

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

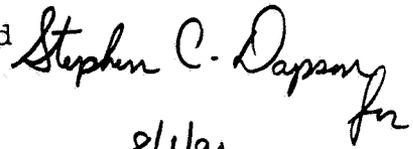
SUBJECT: Fipronil: Review of Additional Toxicology Data Submitted by the Registrant.

P.C. Code: 129121  
Submission: S467904  
MRID No: 432537-01  
DP Barcode: D204398

FROM: Timothy F. McMahon, Ph.D., Pharmacologist   
Review Section I, Toxicology Branch II  
Health Effects Division (7509C)

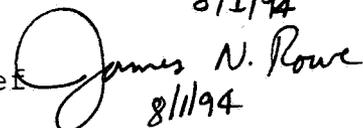
TO: Daphne Waldo / PM 10  
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THRU: Yiannakis M. Ioannou, Ph.D., Section Head  
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for

and

 Marcia Van Gemert, Ph.D., Branch Chief  
Toxicology Branch II  
Health Effects Division (7509C)

8/1/94  
  
8/1/94

Registrant: Rhone Poulenc Agriculture, Ongar, Essex

Action Requested: Review of additional data submitted for a rat metabolism study conducted with Fipronil for an EUP food/feed use.



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Data Summary:

A study entitled, "(14-C)-M&B 46,030: Absorption, Distribution, Metabolism, and Excretion in the Rat " was submitted for review (MRID # 429186-55). This study was conducted at Hazleton UK for Rhone Poulenc Agriculture and was completed in June of 1992. The study was given a core grade of minimum by the Agency, with a request that data on urinary and fecal metabolites be reformatted and submitted. These data were requested based on the observation that the original data were not reported in terms of percent administered dose, and made it difficult to account for all or most of the urinary and fecal radioactivity excreted.

The present submission was submitted in order to comply with this request. Based on the information given, a revised table of urinary metabolites of Fipronil is presented and attached to this review, which replaces the original Table 4 of the review of MRID 429186-55. The fecal data presented clarifies that the original fecal metabolite data reported did represent the percent of the dose. The original rat metabolism study, MRID # 429186-55, remains core minimum data.

(Revised) Table 4 [MRID # 429186-55]  
Urinary Metabolites in <sup>14</sup>C-Fipronil Treated Rats

	<u>LDM</u>	<u>LDF</u>	<u>RDM</u>	<u>RDF</u>	<u>HDM</u>	<u>HDF</u>
U1	ND	ND	0.351	1.21	0.137	0.106
U2	ND	ND	ND	ND	ND	0.115
U3	ND	ND	0.218	0.362	0.526	0.154
U4	ND	ND	0.824	0.382	1.06	0.184
U5	ND	ND	0.508	0.150	1.07	0.279
U6	ND	ND	ND	ND	0.039	ND
U7	ND	ND	1.19	1.03	0.496	0.200
U8	0.352 <sup>a</sup>	1.26	0.491	1.01	1.74	1.73
U9	ND	ND	ND	ND	0.686	0.094
U10	0.465	0.54	4.40	3.60	4.35	0.682
U11	ND	0.67	ND	0.242	1.69	3.29
U12	0.180	0.063	3.80	3.68	6.57	1.40
U13	ND	ND	ND	ND	3.69	0.218
U14	ND	ND	ND	0.249	ND	4.50
U15	ND	0.075	0.279	0.557	2.06	2.90
U16	0.351	ND	ND	0.466	0.966	1.92
U17	0.121	0.026	0.681	1.24	2.92	2.00
U18	ND	ND	ND	0.046	ND	ND
Total % (time)	1.29 (0-72)	2.63 (0-24)	12.74 (0-72)	14.22 (0-96)	28.00 (0-96)	19.77 (0-120)

Data obtained from MRID # 432537-01.