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

DEC 19 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Oxyfluorfen.** Questions Regarding CBRS Review of Analytical Method, Rohm Haas Company Letter Dated 12/12/95. No MRID # DP Barcode D221731 CBRS #16622

FROM: Steven A. Knizner, Chemist
Special Review Section I
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Health Effects Division (7509C)

THRU: Andrew Rathman, Section Head
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TO: Mark Wilhite, PM Team 53
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In a letter to the Agency dated 12/12/95, Rohm Haas Company responded to two deficiencies noted in the CBRS review of the oxyfluorfen analytical method (S.Knizner, 8/17/95, D207134, CBRS #14321 and 14323). The deficiencies (numbering as in original review) and the registrant's responses are found below.

Deficiency: 4. CBRS notes that the Restek columns used for analysis and confirmation are of generally similar polarity (Rtx 200 = trifluoropropylmethyl and Rtx-50 = 50% methyl/50%phenyl polysiloxane respectively) and both GLC techniques use ECD. CBRS would prefer if GC/MS with selected ion monitoring be used for confirmation. If the registrant does not develop an acceptable alternative confirmatory method, interference testing will be necessary.

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Registrant's Response: The registrant inquired that since tolerances are to be established on oxyfluorfen per se, will it be sufficient to perform GC/MS with selected ion monitoring for oxyfluorfen per se, and not the isomers analyzed for in the analytical method? Confirmation for oxyfluorfen is in progress and results will be available shortly.

CBRS Response: A confirmatory GC/MS method for oxyfluorfen per se will suffice.

Deficiency: 27. Radiovalidation - The method was not radiovalidated using egg samples from the metabolism study. This is a deficiency. Eggs from the poultry metabolism study contained 1.037 and 1.026 ppm ^{14}C-oxyfluorfen (chlorophenyl and nitrophenyl ring labeled respectively). The registrant must submit radiovalidation data for this method.

Registrant's Response: Eggs from the poultry metabolism study have been discarded and thus are not available for analysis. The registrant requests as an alternative to perform repetitive extraction and analysis of egg samples from the poultry magnitude of the residue study to accurately measure residues of oxyfluorfen per se in egg tissue.

CBRS Response: CBRS has previously reviewed the poultry magnitude of the residue study (S.Knizner, 8/19/94, D200532, CBRS #13395, MRID #43152202). Results for eggs are summarized below:

Uncorrected residues of oxyfluorfen and its isomers in eggs and tissues of laying hens dosed at 0.086 ppm (2x), 0.345 ppm (7x), and 1.21 ppm (24x) oxyfluorfen for 28 days.

Matrix	Dosing Level	ppm Oxyfluorfen
Eggs [a]	2X	<0.003-0.024
	7X	<0.003-0.057
	24X	<0.003-0.217

[a] Results represent analyses of triplicate egg samples collected on days 1, 3, 7, 10, 14, 17, 21, and 28.

Provided that the registrant reanalyze eggs samples **containing measurable residues of oxyfluorfen per se**, CBRS has no objections to the registrant's proposal. At a minimum, three different samples, **containing measurable residues,** should be analyzed three times each. A comparison to residue levels obtained in the original magnitude of the residue study should also be presented.

Additionally, eggs should be one of the matrices included in the independent laboratory validation (ILV) of the meat/milk/poultry analytical method. NOTE: in the S.Knizner, 8/19/94 review, the registrant was informed that, "The residue methods tested in this study represent a substantial modification of Method II in PAM, Vol. II. Therefore, if the registrant is proposing these methods as tolerance enforcement methods, an independent laboratory validation (described in PR Notice

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88-5, dated 7/15/88) of Methods TR 34-93-17 and TR 34-93-72 must be submitted. Non-confidential copies of the methods must also be submitted for Agency validation." The requirement for an ILV of the meat/milk/poultry analytical methods was also restated in the CBRS review dated 11/15/94 (S.Knizner, D207134, CBRS #14321 and 14323).

cc: S.F., circ., R.F., List B File, S.Knizner
RDI: A. Rathman, 12/18/95 R.Perfetti, 12/19/95 E.Zager, 12/19/95
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