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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 2, 2003

Reviewers:

William T. Drew, Chemist — Date: 8/20/03
Reviewer
RAB2/HED (7509C)

Henri P. Bietlot, Chemist — Date: July 16/03
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FREAS, HED, PMRA

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RAB2/HED (7509C)

Ariff Ally — Date: July 25/03
Section Head
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DP Barcode: D278386

Petition: 1F06313

Citation: 45405107 Fomenko, J. (2001) PAM I Multiresidue Testing for BAS 510 F and its Hydroxy Metabolite (M 510 F01): Lab Project Number: A054.006: 2001/5000875: 46647. Unpublished study prepared by Maxim Technologies, Inc. 89 pages.

Sponsor: BASF Corporation

Background

The information contained herein was compiled by Dynamac Corporation (20440 Century Boulevard, Suite 100, Germantown MD 20874), contractor, under the supervision of RAB2/HED. This DER has undergone secondary review by RAB2, and reflects current HED and Office of Pesticide Programs (OPP) policies. This DER has also been peer-reviewed by PMRA/Canada.

Executive Summary

Residues of BAS 510 F and its metabolite M510F01 were not adequately recovered using the multiresidue methods. BAS 510 F and M510F01 were not evaluated by Protocol A because

neither analyte incorporates an N-methylcarbamate structure, and BAS 510 F was not evaluated by Protocol B since it is not an acid or a phenol. Methylated M510F01 was recovered at ~55% from Protocol B Florisil, and M510F01 was recovered at ~95% from Protocol B GPC. However, the response of methylated M510F01 at levels necessary to quantify recovery under this protocol was inconsistent and non-linear, therefore no additional work was performed. BAS 510 F and M510F01 had good responses with GC/ECD on a DB-1 column at standard and elevated temperature GC conditions under Protocol C. BAS 510 F and M510F01 were not recovered at ≥30% using Protocols D, E, and F. These data will be forwarded to the FDA for further evaluation.

GLP Compliance

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. The petitioner stated that reference standards of chlorpyrifos, ethion, p,p'-DDT, phosalone, and permethrin for the testing of Protocol C were purchased commercially and were not characterized according to GLP standards. The standards used were believed to be of highest quality; this deviation was not expected to impact the study results or their interpretation.

1. Test Substances

Table 1.1.1. List of Analytes Tested.		
Common Name:	Nicobifen, proposed (parent compound)	Hydroxy metabolite
IUPAC Name:	2-Chloro-N-(4'-chlorobiphenyl-2-yl)-nicotinamide	2-Chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)-nicotinamide
CAS Name:	3-Pyridinecarboxamide, 2-chloro-N-(4'chloro[1,1'-biphenyl]-2-yl)-	Not available
CAS Number:	188425-85-6	Not available
Company Name:	BAS 510 F	M510F01
Other Synonyms:	BASF Registry No. 300355	BASF Registry No. 398794

2. Results

Table 2.1. Results of Multiresidue Methods Testing with BAS 510 F and its metabolite M510F01.			
PAM I Protocol	Analyte	Results	Comments
A	BAS 510 F	Not evaluated because neither analyte incorporates an N-methylcarbamate structure.	
	M510F01		
B	BAS 510 F	Not evaluated because it is not an acid or a phenol.	

Table 2.1. Results of Multiresidue Methods Testing with BAS 510 F and its metabolite M510F01.

PAM I Protocol	Analyte	Results	Comments
	M510F01 (and methylated M510F01)	Methylated M510F01 recovered ~55% from Protocol B Florisil; M510F01 recovered ~95% from Protocol B GPC.	The response of methylated M510F01 at levels necessary to quantify recovery under this protocol was inconsistent and non-linear, therefore no additional work was performed.
C	BAS 510 F	Good response with GC/ECD on a DB-1 column at standard and elevated temperature GC conditions.	Only the DB-1 column in combination with ECD was used because responses were good for both analytes using this system.
	M510F01 (and methylated M510F01)		
D	BAS 510 F	Not recovered at ≥30% through Protocol D Florisil using either methylene chloride or mixed ether elution systems.	No additional work was performed with BAS 510 F or M510F01.
	M510F01		
E	BAS 510 F	Not recovered at ≥30% through Protocol E Florisil using either methylene chloride or mixed ether elution systems.	No additional work was performed with BAS 510 F or M510F01.
	M510F01		
F	BAS 510 F	Not recovered at ≥30% through Florisil using either methylene chloride or mixed ether elution systems.	No additional work was performed with BAS 510 F or M510F01.
	M510F01		

3. Discussion

Residues of BAS 510 F and its metabolite M510F01 were not adequately recovered using the multiresidue methods. BAS 510 F and M510F01 were not evaluated by Protocol A because both analytes do not contain an N-methylcarbamate structure, and BAS 510 F was not evaluated by Protocol B since it is not an acid or a phenol. Methylated M510F01 was recovered at ~55% from Protocol B Florisil, and M510F01 was recovered at ~95% from Protocol B GPC. However, the response of methylated M510F01 at levels necessary to quantify recovery under this protocol was inconsistent and non-linear, therefore no additional work was performed. BAS 510 F and M510F01 had good responses with GC/ECD on a DB-1 column at standard and elevated temperature GC conditions under Protocol C. BAS 510 F and M510F01 were not recovered at ≥30% using Protocols D, E, and F. These data will be forwarded to the FDA for further evaluation.

4. Deficiencies

None.

5. References

None.