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: 9/16/03
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FREAS, HED, PMRA

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Branch Senior Scientist
RAB2/HED (7509C)

Ariff Ally — Date: July 25/03
Section Head
FREAS, HED, PMRA

DP Barcode: D278386

Petition: 1F06313

Citation: 45405104 Grosshans, F. (2001) The Stability of BAS 510 F and the Metabolites M510F01, M510F49, M510F51 and M510F53 in Acetonitrile: Final Report: Lab Project Number: 42393: 2000/1017225. Unpublished study prepared by BASF Aktiengesellschaft. 36 pages.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

The petitioner has submitted a study to demonstrate the stability of standard solutions of BAS 510 F and its metabolites in acetonitrile (ACN). Equal amounts of BAS 510 F, M510F01,

(1)

M510F49, M510F51, and M510F53 stock solutions prepared in ACN were combined and diluted with additional ACN to a final concentration of 1 ppm for each analyte. The recoveries of BAS 510 F, M510F01, M510F49, M510F51, and M510F53 following 62 days of storage, either refrigerated in the dark or at room temperature with daylight exposure, indicated no loss of concentration during storage. Based on these data, the petitioner recommends that standard solutions not be stored longer than 60 days.

The recommendation for storage of standard solutions should be added to each method for determination of BAS 510 F and metabolite residues.

GLP Compliance

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. The petitioner stated that the study was conducted in accordance with the GLP regulations established in Germany (Appendix 1 to §19a Section 1, Chemikaliengesetz of 25-July-1994; Official Bulletin/Federal Republic of Germany I 1994, page 1703) instead of U.S. EPA GLP regulations.

1. Materials and Methods

1.1. Test Substances

Table 1.1.1. List of Analytes Tested for Standard Stability in ACN.

Common Name:	Nicobifen, proposed (parent compound)	None assigned (metabolite)	None assigned (metabolite)	None assigned (metabolite)	None assigned (metabolite)
IUPAC Name:	2-Chloro-N-(4'-chlorobiphenyl-2-yl)-nicotinamide	2-Chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)-nicotinamide	–(4'-chloro-biphenyl-2-yl)-2-hydroxy-nicotinamide	–(4'-chloro-5-hydroxy-biphenyl-2-yl)-2-hydroxy-nicotinamide	–(4'-chloro-biphenyl-2-yl)acetamide
CAS Name:	3-Pyridine-carboxamide, 2-chloro-N-(4'chloro [1,1'-biphenyl]-2-yl)-	Not available	Not available	Not available	Not available
CAS Number:	188425-85-6	Not available	Not available	Not available	Not available
Company Name:	BAS 510 F	M510F01	M510F49	M510F51	M510F53
Other Synonyms:	BASF Registry No. 300355	BASF Registry No. 398794	BASF Registry No. 391572	BASF Registry No. 4035208	BASF Registry No. 4035210

1.2. Methods

A study was conducted to demonstrate the stability of standard solutions in ACN. Equal amounts of BAS 510 F, M510F01, M510F49, M510F51, and M510F53 stock solutions prepared in ACN were combined and diluted with additional ACN so as the final concentration was 1 µg/mL for each analyte. Separate aliquots of the combined standard solution in ACN were stored refrigerated (~4° C) in the dark and at room temperature with daylight exposure. The stored samples were analyzed for residues of BAS 510 F, M510F01, M510F49, M510F51, and M510F53 following 0, 1, 7, 14, 33, and 62 days of storage. Samples were analyzed using an HPLC method which utilizes a Superspher 60 PR-select B column, UV detection (254 nm), and a gradient mobile phase of ammonium formate in water and ACN. Quantitation was based on calibration curves of freshly prepared BAS 510 F, M510F01, M510F49, M510F51, and M510F53 standards in HPLC mobile phase.

2. Results

2.1. Stability of Reference Materials

The concentrations of BAS 510 F, M510F01, M510F49, M510F51, and M510F53 following 62 days stored either refrigerated (~4° C) in the dark or at room temperature with daylight exposure indicated no loss of concentration. Average recoveries of duplicate samples are reported below.

Table 2.1.1. Storage Stability of BAS 510 F, M510F01, M510F49, M510F51, and M510F53 in ACN at 1 ppm each analyte.

Storage, days	Recovery, %[1]				
	BAS 510 F	M510F01	M510F49	M510F51	M510F53
Stored Refrigerated (4° C) in the Dark					
0	102	102	96	100	101
1	102	102	96	100	100
7	105	101	105	99	102
14	104	107	101	96	103
33	98	100	97	97	99
62	103	103	103	102	102
Stored at Ambient Conditions, Exposed to Daylight					
0	104	103	98	101	102
1	105	105	100	102	104
7	105	102	105	100	103
14	105	106	101	95	102
33	96	97	95	94	96
62	105	103	103	101	103

[1] Recovery is average of duplicate samples; % recovery was calculated by the study reviewer from the concentration reported in µg/mL.

2.2. Method Characteristics

Not applicable to this submission.

3. Discussion

The recoveries of BAS 510 F, M510F01, M510F49, M510F51, and M510F53 following 62 days of storage, either refrigerated in the dark or at room temperature with exposure to daylight, indicated no loss of concentration during storage. Based on these data the petitioner recommends that standard solutions not be stored longer than 60 days.

The recommendation for storage of standard solutions should be added to each method for determination of BAS 510 F and metabolite residues.

4. Deficiencies

None.

5. References

None.