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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 2, 2003

Reviewers:

M. Nelson Date: 9.2.03
Maxie Jo Nelson, Chemist
Reviewer
RAB2/HED (7509C)

Date: 7/16/03
Henri P. Bietlot, Chemist
Peer reviewer
FREAS, HED, PMRA

R. Loranger Date: 8/15/03
Richard A. Loranger
Branch Senior Scientist
RAB2/HED (7509C)

Date: 7/25/03
Ariff Ally
Section Head
FREAS, HED, PMRA

DP Barcode: D278386

Petition: 1F06313

Citation: 45405109 Funk, H.; Mackenroth, C. (2001) Investigation of the Stability of Residues of BAS 510 F in Plant Matrices under Normal Storage Conditions: Lab Project Number: 41851: 200/1014855. Unpublished study prepared by BASF Aktiengesellschaft. 33 p.

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 was also peer-reviewed by PMRA.

Executive Summary

BASF Corporation has submitted a storage stability study of BAS 510 F residues in plant commodities. Representative crop matrices (sugar beet root, cabbage, oilrape (canola) seed, pea, peach, and wheat forage, grain, and straw) were fortified with BAS 510 F at 0.5 ppm and stored

frozen (-20 C). Fortified samples were analyzed for residues of BAS 510 F using LC/MS/MS method 445/0 following 0, 1, 3, 6, and 12 months of frozen storage. The petitioner stated that the current submission is an interim report and that additional samples are to be analyzed following 18 and 24 months of frozen storage.

When the final report of this storage stability study is submitted, the petitioner should include a description of the fortification solutions used in the study and a full description of the analytical method. These data gaps are not expected to have an impact on the storage stability results. Submission of the final report may be made a condition of registration.

The submitted storage stability data indicate that residues of BAS 510 F are stable for up to 356 days (~12 months) in/on sugar beet root, cabbage head, oilrape (canola) seed, pea, peach, and wheat forage, grain, and straw under frozen storage conditions.

The storage stability study adequately demonstrates the stability of residues of BAS 510 F in diverse representative crop matrices for up to ~1 year of frozen storage.

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, p. 1703) instead of U.S. EPA GLP regulations.

1. Materials and Methods

1.1. Test Substances

Table 1.1.1. List of Analytes Tested.	
Common Name:	Nicobifen (ISO, proposed)
IUPAC Name:	2-Chloro-N-(4'-chlorobiphenyl-2-yl)-nicotinamide
CAS Name:	3-Pyridinecarboxamide, 2-chloro-N-(4'chloro[1,1'-biphenyl]-2-yl)-
CAS Number:	188425-85-6
Company Name:	BAS 510 F
Other Synonyms:	BASF Registry No. 300355

1.2. Methods

Untreated samples of representative crops (cabbage, oilrape seed, pea, peach, sugar beet root, wheat forage, grain and straw) were fortified with BAS 510 F standard (99.3% purity) at 0.5 ppm. The carrier solvent and equilibration time were not provided. Prior to fortification, wheat

forage samples were ground, seed and grain samples were sieved and mixed, straw was milled, and sugar beets, cabbage heads, and fruits were cut. Fortified and unfortified samples were stored in polyethylene containers at approximately -20 C in the dark. Control and fortified samples were analyzed for residues of BAS 510 F using LC/MS/MS method 445/0 following 0, 1, 3, 6, and 12 months of frozen storage. Using the LC/MS/MS method 445/0, residues were extracted with methanol, water, and HCl, and partitioned with cyclohexane; the limit of quantitation was 0.05 ppm. A full description of the method was not included in the submission. Fresh fortification samples were also analyzed with the stored samples to generate concurrent method recoveries. The petitioner stated that this submission is an interim report and that additional samples are to be analyzed following 18 and 24 months of frozen storage.

2. Results

2.1. Stability in the Commodity

Table 2.1.1. Storage Stability of BAS 510 F in Agricultural Commodities Fortified with BAS 510 F at 0.5 ppm and Stored Frozen (-20 C) in the Dark.

Commodity	Storage Period (days)	Concurrent Spike Recovery (%)[1]	Apparent Recovery in Stored Sample (%)[2]	Corrected Recovery in Stored Sample (%)[3]
Beet, sugar, root	0	84.6, 86.8 (85.7)	84, 88	--
	33	95.6, 97.0 (96.3)	90, 94	93, 97
	96	91.5, 96.2 (93.9)	87, 93	93, 99
	182	73.2, 96.8 (85.0)	95, 100	112, 117
	356	94.0, 95.7 (94.9)	98, 99	103, 104
Cabbage, white	0	81.7, 101.6 (91.7)	90, 96	--
	33	88.6, 97.0 (92.8)	86, 87	92, 94
	96	94.0, 120.0 (107.0)	111, 112	104, 104
	182	85.6, 93.3 (89.5)	93, 95	104, 106
	356	94.0, 95.0 (94.5)	93, 95	98, 100
Oilrape seed (canola seed)	0	77.1, 110.3 (93.7)	73, 78	--
	33	107.7, 116.0 (111.9)	90, 91	80, 82
	96	89.1, 90.1 (89.6)	79, 82	88, 91
	182	94.4, 99.2 (96.8)	85, 87	88, 89
	356	90.4, 92.7 (91.6)	84, 84	92, 92
Pea	0	89.1, 89.2 (89.2)	87, 88	--
	33	92.2, 101.4 (96.8)	94, 96	97, 99
	96	79.4, 79.4 (79.4)	86, 88	108, 111
	182	95.4	94, 98	99, 103
	356	97.5, 101.5 (99.5)	100, 102	101, 102

Commodity	Storage Period (days)	Concurrent Spike Recovery (%)[1]	Apparent Recovery in Stored Sample (%)[2]	Corrected Recovery in Stored Sample (%)[3]
Peach	0	82.8, 87.3 (89.1)	89, 92	--
	33	95.1, 100.2 (97.7)	83, 95	85, 97
	96	86.9, 91.8 (89.4)	89, 90	99, 101
	182	94.8, 100.0 (97.4)	97	99
	356	92.8, 94.0 (93.4)	91, 101	97, 108
Wheat, forage	0	87.1, 88.5 (87.8)	84, 98	--
	33	82.0, 95.8 (88.9)	80, 80	89, 89
	96	84.6, 93.5 (89.1)	86, 89	96, 100
	182	98.6, 101.4 (100.0)	91, 96	91, 96
	356	74.8, 91.0 (82.9)	88, 90	106, 108
Wheat, grain	0	88.7, 96.1 (92.4)	87, 91	--
	33	103.0, 106.7 (104.9)	84, 85	80, 81
	96	93.8, 97.4 (95.6)	86	90
	182	98.0, 104.2 (101.1)	91, 93	90, 92
	356	98.2, 99.4 (98.8)	90, 94	92, 95
Wheat, straw	0	74.6, 87.4 (81.0)	79, 81	--
	33	68.4, 89.3 (78.9)	82, 84	104, 107
	96	84.6, 86.1 (85.4)	82, 89	96, 104
	182	100.9, 106.1 (103.5)	95, 96	91, 93
	356	92.5, 93.7 (93.1)	92, 92	99, 99

[1] Average fresh fortification recoveries are presented in parentheses.
[2] Residues were reported by the petitioner in mg/kg; % recoveries were calculated by Dynamac.
[3] Corrected residues were reported by the petitioner in mg/kg; % recoveries were calculated by Dynamac.

3. Discussion

The submitted storage stability data indicate that residues of BAS 510 F are stable for up to 356 days (~12 months) of frozen storage in/on sugar beet root, cabbage head, oilrape seed, pea, peach, and wheat forage, grain, and straw.

4. Deficiencies

A full description of the analytical method was not included in the submission. In addition, the solvent used in the fortification solutions was not specified. These data gaps are not expected to have an impact on the storage stability results. When the final report of this storage stability

study is submitted, the petitioner should include a description of the fortification solutions used in the study and a full description of the analytical method.

5. References

None.