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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 2, 2003

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DP Barcode: D278386

Petition: 1F06313

Citation: 45405108 Grosshans, F. (2001) Investigation of the Stability of Residues of BAS 510 F and MF510F01 in Sample Material of Animal Origin Under Usual Storage Conditions: Final Report: Lab Project Number: 42403: 2000/1017229. Unpublished study prepared by BASF Aktiengesellschaft. 47 p.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 residues of BAS 510 F and its hydroxy metabolite M510F01 in ruminant commodities. Samples of milk and homogenized cow liver and muscle were fortified with BAS 510 F and M510F01 at 0.5 ppm each and stored frozen

(≤-18 C). Fortified samples were analyzed for residues of BAS 510 F and M510F01 using LC/MS/MS method 471/0 following 0, 62/63, 103, and 166/167 days of frozen storage.

The submitted storage stability data indicate that residues of BAS 510 F and its metabolite M510F01 are stable for up to 166 days (~5.5 months) in cow milk, liver, and muscle. As stated in the OPPTS 860.1380 Guidelines, when residues are stable in these matrices, analyses of other tissues (fat, kidney) are not required.

The storage stability study adequately demonstrates the stability of residues of BAS 510 F and M510F01 in ruminant matrices for up to 5.5 months 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)	None assigned (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

1.2. Methods

Samples of cow milk, liver, and muscle, obtained commercially, were fortified with BAS 510 F and its metabolite M510F01 in methanol at 0.5 ppm each. Prior to fortification, tissue samples were homogenized in a meat grinder. Fortified and unfortified samples were stored in polyethylene containers at ≤-18 C. Control and fortified samples were analyzed for residues of BAS 510 F and M510F01 using LC/MS/MS method 471/0 following 0, 62/63, 103, and 166/167 days of frozen storage; a full description of method 471/0 may be found in the data evaluation record for MRID 45405106. Fresh fortification samples were also analyzed with the stored samples to generate concurrent method recoveries.

2. Results

2.1. Stability in the Commodity

Table 2.1.1. Storage Stability of BAS 510 F and M510F01 in Ruminant Commodities Fortified with Each Compound at 0.5 ppm and Stored Frozen (≤-18 C).

Commodity	Analyte	Storage Period (days)	Concurrent Spike Recovery (%)[1]	Apparent Recovery in Stored Sample (%)[2]	Corrected Recovery in Stored Sample (%)[3]
Milk	BAS 510 F	0	87.3, 88.4 (87.8)	92.0, 92.8	--
		62	85.7, 94.9 (90.3)	91.5, 91.7	101, 102
		103	91.5, 93.1 (92.3)	84.4, 88.2	91.4, 95.5
		167	[87.3, 88.4 (87.8)]	85.5, 90.0	97.3, 102
Liver		0	80.0, 81.3 (80.7)	79.9, 84.2	--
		63	70.3, 75.2 (72.7)	68.0, 79.6	93.5, 109
		103	74.8, 84.5 (79.6)	76.3, 79.1	95.8, 99.3
		167	[80.0, 81.3 (80.7)]	75.4, 80.1	93.4, 99.3
Muscle		0	85.0, 87.8 (86.4)	85.0, 90.4	--
		62	83.1, 88.6 (85.8)	83.6, 88.6	97.4, 103
		103	87.9, 88.0 (87.9)	79.7, 80.8	90.6, 91.9
		166	[85.0, 87.8 (86.4)]	87.9, 92.4	102, 107
Milk	M510F01	0	89.9, 93.1 (91.5)	89.9, 94.0	--
		62	92.8, 95.5 (94.2)	89.5, 91.8	95.1, 97.5
		103	90.3, 94.5 (92.4)	91.3, 93.5	98.8, 101
		167	[89.9, 93.1 (91.5)]	92.4, 92.7	101, 101
Liver		0	79.2, 82.7 (80.9)	74.6, 87.2	--
		63	75.9, 79.4 (77.7)	76.2, 80.2	98.1, 103
		103	81.6, 87.8 (84.7)	85.9, 88.4	101, 104
		167	[79.2, 82.7 (80.9)]	71.9, 78.6	88.9, 97.1
Muscle		0	84.3, 87.9 (86.1)	82.5, 87.7	--
		62	88.8, 88.8 (88.8)	80.2, 85.9	90.3, 96.7
		103	83.4, 89.7 (86.5)	80.8, 82.0	93.4, 94.8
		166	[84.3, 87.9 (86.1)]	74.1, 80.4	86.1, 93.5

[1] Average fresh fortification recoveries are presented in parentheses. The 0-day and 166/167-day samples were analyzed on the same day; therefore, the fresh fortification recoveries reported for the 0-day samples apply also to the 166/167-day samples.

[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 and its metabolite M510F01 are stable for up to 166/167 days (~5.5 months) in cow milk, liver, and muscle. As stated in the OPPTS 860.1380 Guidelines, when residues are stable in these matrices, analyses of other tissues (fat, kidney) are not required.

4. Deficiencies

None.

5. References

None.