

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 No.: 1F06313

Citation:

45405202 Wofford, J.; Abdel-Baky, S. (2001) The Magnitude of BAS 510 F

Residues in Plum Processed Fractions: Final Report: Lab Project Number: 63906:

2000/5275. Unpublished study prepared by BASF Corporation. 70 p.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 data depicting the potential for concentration of residues of BAS 510 F in the processed commodities of plum. In a single field trial conducted in CA, plums were harvested on the day of the last of five foliar spray applications of the 70% WG formulation at ~1.15 lb ai/A/application (1.29 kg ai/ha/application), with a 7-day retreatment interval, for a total rate of 5.73 lb ai/A (6.42 kg ai/ha). Plums, bearing BAS 510 F residues of 0.677 and 1.09

ppm, were processed into washed plums and prunes using simulated commercial processing procedures.

The processing data indicate that residues of BAS 510 F reduce in prunes (0.407 and 0.514 ppm; 0.46 and 0.58x; average processing factor of 0.52x).

Residues of BAS 510 F in/on unwashed plums (RAC) and its processed commodities were quantitated using LC/MS/MS method D9908, the data collection method for plant commodities. Acceptable concurrent method validation data for plums and its processed commodities were included in the submission.

Plum samples were processed within 21 days of harvest, samples of plums and prunes were stored frozen (≤-10°C) for up to 99 and 78 days, respectively, prior to analysis. Adequate storage stability data on diverse crops are available to support the storage conditions and intervals of the RAC samples (refer to the DER for MRID 45405109) and, by extension, to support the storage conditions of the processed plum commodities.

The submitted processing study is considered acceptable to demonstrate the potential for concentration of BAS 510 F residues in the processed commodities of plums.

GLP Compliance

Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. No GLP deviations were reported which would impact the study results or their interpretation.

BAS 510 F Plum PMRA a.i. code (CCH) Processed Food/Feed OPPTS 860.1520 DACO 7.4.5

PC Code: 128008 MRID: 45405202 Submission # 2001-1027, 1036, 1043

1. Materials and Methods

1.1. Test Substance

Active Ingredient

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

Structure:

1.2. Processing Information

In a single field trial conducted in CA in 1999, plums were harvested on the day of the last of five foliar spray applications of the 70% WG formulation at ~1.15 lb ai/A/application (1.29 kg ai/ha/application), with a 7-day retreatment interval, for a total rate of 5.73 lb ai/A (6.42 kg ai/ha). The field trial included two additional treatment plots, where plums were treated at lower application rates [~0.23 lb ai/A/application (~0.26 kg ai/ha/application), for a total rate of 1.15 lb ai/A (1.29 kg ai/ha) and ~0.69 lb ai/A/application (~0.77 kg ai/ha/application), for a total rate of 2.74 lb ai/A (3.07 kg ai/ha)] to provide backup samples in case phytotoxicity occurred at the higher exaggerated rate. Since no phytotoxicity resulted from the highest exaggerated treatment rate, samples from the lower treatment rates were not harvested, processed, and/or analyzed. A single untreated and duplicate treated samples (from the highest exaggerated application rate) were collected and shipped at ambient temperatures on the day of harvest to The National Food Laboratory (Dublin, CA).

Samples of plums were processed according to simulated commercial procedures into prunes. Briefly, plums were cleaned by removing stems, leaves, and twigs, and then immersed in cold water (24-28°C) and stirred with a paddle. A subsample of washed plums was collected and frozen. The remaining washed plums were then dried to ≤25% moisture in a forced air dryer. The dried samples were placed in sealed plastic bags and stored at room temperature (20-21°C) for 14-19 days to simulate sweat-box storage. Following storage, prune samples were rehydrated to 26.4-27.84% moisture by immersion in water (typical retail moisture is 28-32%) and then returned to storage at 21°C for 25-28 hours to allow moisture equilibration. Prune samples

were removed from storage and frozen. Material balance (weight distributions) and process flow charts were provided.

1.3. Post-Processing Procedures

Plum samples were held in cool storage (18-19°C) prior to processing and were processed within 21 days of harvest. After processing samples were shipped frozen to BASF Agro Research (Research Triangle Park, NC) for analysis.

Table 1.3.1. Summary of Storage Conditions.							
Matrix	Processed Commodity or Extract	Storage Temperature (*C) (Analytical Laboratory)	Duration				
Plum	Plum, unwashed (RAC)	<-10	97-99 days (3.2-3.3 months)				
	Plum, washed	<-10	76-78 days (2.5-2.6 months)				
	Prune	<-10	76-78 days (2.5-2.6 months)				

1.4. Analytical Methods

Samples of plums (RAC) and its processed fractions of washed plums and prunes were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, (the data collection method for plant commodities). Briefly, samples of plums and prunes were extracted with methanol:water (70:30, v:v) and filtered. An aliquot of the filtrate was cleaned up using C18 solid phase extraction (SPE). Residues were eluted with dichloromethane (DCM) and cleaned up further using silica gel SPE. Residues were eluted with 4% ethyl acetate in DCM. The eluate was evaporated and residues were redissolved in ammonium formate:formic acid for analysis by LC/MS/MS; refer to the DER for MRID 45405027 for a complete description of the quantitation procedures.

The limit of detection (LOD) was 0.025 ppm, and the validated limit of quantitation (LOQ) was 0.05 ppm for the residues of BAS 510 F in/on plums and prunes.

2. Results

Table 2.1. Summary of Concurrent Analytical Method Validation.							
Commodity	Fortification Level (ppm)	Recoveries (%)	Mean Recovery				
Plum, unwashed (RAC)	0.05, 1.0	86,91	3 44 89				
Plum, washed	0.05, 1.0	82, 90	86				
Prime 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	0.05, 1.0	76, 92	84				

BAS 510 F

Plum

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Table 2.2. Residue Data from Plum Processing Study with BAS 510 F.								
RAC	Processed Commodity	Total Rate (lbs ai/A)	PHI (days)	Residues (ppm)	Processing Factor			
Plum	Plum, unwashed (RAC)	5.73	0	0.677, 1.09 (0.882)				
	Plum, washed			0.427, 0.968				
	Prune			0.407, 0.514	0.46x, 0.58x			

Average result reported in parentheses.

Apparent residues were less than the method LOQ (<0.05 ppm) in/on one sample of untreated unwashed plum (RAC), and one sample each of washed plum and prune processed from untreated plums.

3. Discussion

3.1. Methods

Mature plums were harvested on the day of the last of five foliar spray applications of the 70% WG formulation at ~1.15 lb ai/A/application (~1.29 kg ai/ha/application), with a 7-day retreatment interval, for a total rate of 5.73 lb ai/A (6.42 kg ai/ha). Applications were made using ground equipment in 242-250 gal/A (2708-2801 l/ha) with a spray adjuvant added. The collected samples were processed into prunes using simulated commercial processing procedures.

Residues of BAS 510 F in/on unwashed plums (RAC) and its processed commodities washed plums and prunes were quantitated using LC/MS/MS method D9908, (the data collection method for plant commodities). Acceptable concurrent method validation data for plums and its processed commodities were included in the submission.

Plum samples were processed within 21 days of harvest, samples of plums and prunes were stored frozen (≤-10°C) for up to 99 and 78 days, respectively, prior to analysis. Adequate storage stability data on diverse crops are available to support the storage conditions and intervals of the RAC samples (refer to the DER for MRID 45405109) and, by extension, to support the storage conditions of the processed plum commodities.

3.2. Results

Residues of BAS 510 F were 0.677 and 1.09 ppm in/on treated plums. The processing data indicate that residues of BAS 510 F reduce in prunes (0.407 and 0.514 ppm; 0.46 and 0.58x; average processing factor of 0.52x).

The submitted processing study is considered adequate to demonstrate the potential for concentration of BAS 510 F residues in the processed commodities of plums.

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4. Deficiencies

None

5. References

None