

BAS 510 F
Tomato
PMRA a.i. code (CCH)

Processed Food/Feed
OPPTS 860.1520
DACO 7.4.5

PC Code: 128008
MRID: 45405126
Submission #2001-1027, 1036, 1043



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 2, 2003

Reviewers:

William Cutchin Date: *8/25/03*
William Cutchin, Chemist
Reviewer
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Ariff Ally Date: *July 23/03*
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DP Barcode: D278386

Petition No.: 1F06313

Citation: 45405126 Haughey, D.; Abdel-Baky, S. (2001) The Magnitude of BAS 510 F Residues in Tomato Processed Fractions: Final Report: Lab Project Number: 46788: 2001/5000967: 2000210. Unpublished study prepared by BASF Corporation. 133 p.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 has also been peer-reviewed by PMRA/Canada.

Executive Summary

BASF Corporation has submitted data depicting the potential for concentration of residues of BAS 510 F in the processed commodities of tomato. In four field trials conducted in CA, tomatoes were harvested on the day of the last of two foliar spray applications of the 70% WG formulation at ~2.75 lb ai/A/application (~3.08 kg ai/ha/application), with a 7-day retreatment interval, for a total rate of 5.46-5.56 lb ai/A (6.12-6.23 kg ai/ha). Tomatoes, bearing BAS 510 F residues of 0.62-1.52 ppm, were processed into puree and paste, the currently regulated processed commodities of tomato, as well as washed tomato, wet pomace, canned juice, peeled tomato, canned tomato, and peel using simulated commercial processing procedures.

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

Tomatoes were processed within one day of harvest, and samples of tomatoes, tomato puree, and tomato paste were stored frozen (≤ -10 °C) for up to 147, 131, and 154 days, respectively, prior to analysis. Acceptable storage stability data are available to support the storage conditions and intervals of the RAC samples (refer to the DER for MRID 45405109), but no storage stability data are available to support the storage conditions of tomato puree and paste samples from the submitted tomato processing study. Storage stability data are required to support the storage conditions and intervals of samples of tomato puree (up to 131 days) and paste (up to 154 days) from the submitted tomato processing study. Submission of these data may be made a **condition of registration**.

The processing data indicate that residues of BAS 510 F reduce in puree (0.14-0.54 ppm; 0.19-0.73x; average processing factor of 0.35x) and concentrate slightly in paste (0.47-1.68 ppm; 0.53-2.24x; average processing factor of 1.06x). The observed average processing factor of 1.06x for tomato paste is less than the theoretical maximum concentration factor of 5.5x (OPPTS 860.1520, Table 2).

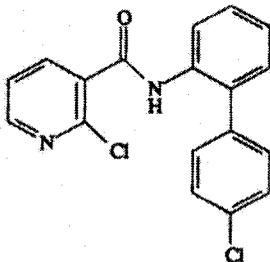
The submitted processing study is considered **acceptable** to demonstrate the potential for concentration of BAS 510 F residues in the processed commodities of tomatoes, provided supporting storage stability data are submitted for the storage intervals of processed tomato puree and paste.

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.

1. Materials and Methods

1.1. Test Substance



BAS 510 F

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

1.2. Processing Information

Tomatoes were obtained from a total of four field trials conducted in CA during the 2000 growing season. Mature tomatoes were harvested on the day of the last of two foliar spray applications of the 70% WG formulation at ~2.75 lb ai/A/application (~3.08 kg ai/ha), with a 7-day retreatment interval, for a total rate of 5.46-5.56 lb ai/A (6.12-6.23 ka ai/ha). A single bulk-sized sample was collected from two untreated tomato plots and from all four treated tomato plots; each bulk sample weighed ≥ 325 lbs (≥ 147 kg). Samples were shipped at ambient temperatures on the day of harvest to The National Food Laboratory (Dublin, CA).

Samples of tomatoes were processed according to simulated commercial procedures into washed tomato, wet pomace, canned juice, puree, paste, peeled tomato, canned tomato, and peel using simulated commercial processing procedures. Briefly, the tomatoes were washed twice, first with municipal water, then with chlorinated water. The wash water was collected and the washed tomatoes were separated into two groups, juice production tomatoes and canning tomatoes. For juice production, washed tomatoes were ground/crushed, heated to 91-94°C, and fed into a finisher and separated into wet pomace and juice. A wet pomace sample was collected and frozen. The juice was separated into three subsamples, tomato juice for canning, juice for canning tomatoes, and juice for condensing into puree. For canned juice, tomato juice was filled into heated cans (72-82°C) and the filled cans were sealed, heated for a minimum of 50 minutes at 117°C, cooled, and frozen. A portion of the remaining juice was concentrated by vacuum evaporation to produce puree, a sample of which was collected, weighed, heated to 91-93°C,

canned, cooled, and frozen. An additional sample of puree was vacuum-condensed to paste. The paste fraction was heated (88-90°C), packed into cans, sealed, and held at filling temperature for 5-19 minutes prior to cooling and then frozen. For canning tomatoes in juice, washed tomatoes were immersed in boiling water and cooled to remove the peel. A peel sample and peeled tomato sample were collected and frozen. The remaining peeled tomatoes were placed in cans and filled with tomato juice at $\geq 78^\circ\text{C}$. The filled cans were sealed, heated for a minimum of 50 minutes at 117°C , cooled, and frozen.

The processing procedure is representative of a small-scaled commercial processing of tomatoes; however, because of the sample size, tomatoes were processed using a batch procedure instead of a continuous procedure, as in commercial production. Material balance (weight distributions) and process flow charts were provided.

1.3. Post-Processing Procedures

Tomato samples were held in cool storage ($18 \pm 5^\circ\text{C}$) prior to processing, which was initiated within one day of harvest. After processing, samples were shipped frozen to BASF Agro Research (Research Triangle Park, NC) for analysis.

Matrix	Processed Commodity or Extract	Storage Temperature ($^\circ\text{C}$) (Analytical Laboratory)	Duration
Tomato	Tomato, unwashed (RAC)	<-10	90-147 days (3.0-4.8 months)
	Wash water	<-10	110-142 days (3.6-4.7 months)
	Tomato, washed	<-10	90-147 days (3.0-4.8 months)
	Wet Pomace	<-10	89-146 days (2.9-4.8 months)
	Canned juice	<-10	89-119 days (2.9-3.9 months)
	Puree	<-10	88-131 days (2.9-4.3 months)
	Paste	<-10	88-154 days (2.9-5.1 months)
	Peeled tomato	<-10	88-119 days (2.9-3.9 months)
	Canned tomato	<-10	88-154 days (2.9-5.1 months)
	Peel	<-10	88-154 days (2.9-5.1 months)

1.4. Analytical Methods

Samples of unwashed tomatoes (RAC) and its processed fractions of washed tomatoes, wet pomace, canned juice, puree, tomato paste, peeled tomatoes, canned tomatoes, and peel were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plant commodities. Briefly, samples of tomatoes and its processed fractions were extracted with methanol:water:2N HCl (70:25:5, v:v:v) using Polytron homogenization. An aliquot of the extract was subjected to liquid/liquid partitioning with saturated sodium chloride and

cyclohexane. An aliquot of the cyclohexane phase was collected and evaporated to dryness. 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 unwashed tomatoes and its processed fractions washed tomatoes, wet pomace, canned juice, puree, tomato paste, peeled tomatoes, canned tomatoes, and peel. Concurrent recoveries for a limited range in spiking levels were fair to good (Table 2.1 below).

2. Results

Commodity	Fortification Level (ppm)	Recoveries (%)	Mean Recovery \pm SD
Tomato, unwashed (RAC)	0.05, 1.00	92, 95, 99	95 \pm 4
Wash water	0.05, 1.00	84, 90	87
Tomato, washed	0.05, 1.00	85, 85, 90	87 \pm 3
Wet Pomace	0.05, 1.00	87, 87, 88	87 \pm 1
Canned juice	0.05, 1.00	93, 94	94
Puree	0.05, 1.00	80, 84, 89, 91	86 \pm 5
Paste	0.05-2.00	77, 79, 84, 87	82 \pm 5
Peeled tomato	0.05, 1.00	79, 131	105
Canned tomato	0.05, 1.00	67, 81, 84	77 \pm 9
Peel	0.05, 1.00	70, 79, 83	77 \pm 7

Table 2.2. Residue Data from Tomato Processing Study with BAS 510 F.					
RAC (Trial location)	Processed Commodity	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	Residues (ppm)	Processing Factor
Tomato (Tulare, CA)	Tomato, unwashed (RAC)	5.51 [6.17]	0	1.52	--
	Wash water			0.20	--
	Tomato, washed			0.21	--
	Wet Pomace			1.42	0.93x
	Canned juice			0.19	0.13x
	Puree			0.36	0.24x
	Paste			0.80	0.53x
	Peeled tomato			<0.05	<0.03x
	Canned tomato			<0.05	<0.03x
	Peel			0.43	0.28x
Tomato (San Joaquin, CA)	Tomato, unwashed (RAC)	5.57 [6.24]	0	0.60, 0.67, 0.87 (0.71) ¹	--
	Wash water			0.14	--
	Tomato, washed			0.55, 0.69, 0.77 (0.67) ¹	--
	Wet Pomace			1.35, 1.63, 1.64 (1.54) ¹	2.17x
	Canned juice			0.19	0.27x
	Puree			0.50, 0.54 (0.52) ¹	0.73x
	Paste			1.48, 1.62, 1.68 (1.59) ¹	2.24x
	Peeled tomato			-- ²	--
	Canned tomato			-- ²	--
	Peel			-- ²	--
Tomato (Glenn, CA)	Tomato, unwashed (RAC)	5.50 [6.16]	0	0.96	--
	Wash water			0.34	--
	Tomato, washed			0.16	--
	Wet Pomace			0.82	0.85x
	Canned juice			0.15	0.16x
	Puree			0.23	0.24x
	Paste			0.79	0.82x
	Peeled tomato			<0.05	<0.05x
	Canned tomato			<0.05	<0.05x
	Peel			0.34	0.35x

RAC (Trial location)	Processed Commodity	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	Residues (ppm)	Processing Factor
Tomato (Madera, CA)	Tomato, unwashed (RAC)	5.46 [6.12]	0	0.75	--
	Wash water			0.05	--
	Tomato, washed			0.11	--
	Wet Pomace			0.82	1.09x
	Canned juice			0.07	0.09x
	Puree			0.14	0.19x
	Paste			0.47	0.63x
	Peeled tomato			<0.05	<0.07x
	Canned tomato			0.09	0.12x
	Peel			0.44	0.59x

¹ Average of duplicate or triplicate analyses of a single sample are reported in parentheses.

² Because of an oversight at the processor, peeled tomatoes, canned tomatoes, and peel samples were not collected.

Apparent residues were less than the method LOQ (<0.05 ppm) in/on two samples of untreated unwashed tomato (RAC), and two samples each of washed tomato, wet pomace, canned juice, puree, paste, peeled tomato, canned tomato, and peel processed from untreated tomatoes.

3. Discussion

3.1. Methods

Mature tomatoes from four field trials were harvested on the day of the last of two foliar spray applications of the 70% WG formulation at ~2.75 lb ai/A/application (~3.08 kg ai/ha/application), with a 7-day retreatment interval, for a total rate of 5.46-5.56 lb ai/A (6.12-6.23 kg ai/ha). Applications were made using ground equipment in a spray volume of 23.6-50.73 gal/A (264.3-568.2 L/ha) of water with a spray adjuvant added. We note that the 70% BAS 510 F WG formulation used in the field trials also contained another experimental active ingredient (BAS 500 F; pyraclostrobin) as part of the tank-mix; data for the BAS 500 F active ingredient were submitted under a separate submission.

The collected samples were processed into paste and puree, the currently regulated processed commodities of tomato, as well as washed tomato, wet pomace, canned juice, peeled tomato, canned tomato, and peel using simulated commercial processing procedures.

Residues of BAS 510 F in/on unwashed tomatoes (RAC) and its processed commodities, washed tomato, wet pomace, canned juice, puree, paste, peeled tomato, canned tomato, and peel, were quantitated using LC/MS/MS method D9908, the data collection method for plant commodities.

Tomatoes were processed within one day of harvest, and samples of tomatoes, tomato puree, and tomato paste were stored frozen ($\leq -10^{\circ}\text{C}$) for up to 147, 131, and 154 days, respectively, prior to analysis. Acceptable storage stability data are available to support the storage conditions and intervals of the RAC samples (refer to the DER for MRID 45405109), but **no storage stability data are available to support the storage conditions of tomato puree and paste samples from the submitted tomato processing study.**

3.2. Results

Residues of BAS 510 F from the four field trials were 0.60-1.52 ppm in/on treated tomatoes. The processing data indicate that residues of BAS 510 F reduce in puree (0.14-0.54 ppm; 0.19-0.73x; average processing factor of 0.35x) and concentrate slightly in paste (0.47-1.68 ppm; 0.53-2.24x; average processing factor of 1.06x).

The observed average processing factor of 1.06x for tomato paste is less than the theoretical maximum concentration factor of 5.5x (OPPTS 860.1520, Table 2). HED will consider the observed processing factor in determining the need for a tolerance on tomato paste.

The submitted processing study is **tentatively considered acceptable** to demonstrate the potential for concentration of BAS 510 F residues in the processed commodities of tomatoes, **pending submission of supporting storage stability data for processed tomato puree and paste.**

4. Deficiencies

Storage stability data are required to support the storage conditions and intervals of samples of tomato puree (up to 131 days) and paste (up to 154 days) from the submitted tomato processing study. Submission of these data can be made a condition of registration.

5. References

None