PP#4574

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

15
FEB 1: 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

SUBJECT: PP# 5G04574. Alert in or on Tomatoes. Evaluation of Residue Data and Analytical Methods. Chemical No 129093. MRID#s 437536-01 thru -04. Barcode D218766. CBTS# 16070.

FROM: G.F. Kramer, Ph.D., Chemist
Tolerance Petition Section I
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: M.S. Metzger, Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: Dennis Edwards, Product Manager
Meredith Johnson, Team 19 Reviewer
Registration Division (7505C)

And

Karen Whitby, Ph.D., Acting Section Head
Registration Section, RCAB
Health Effects Division (7509C)

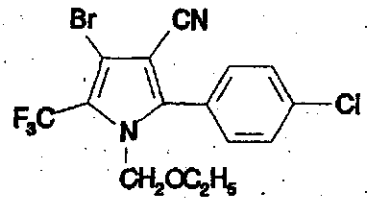
American Cyanamid Company has petitioned for an experimental use permit (EUP) and temporary tolerances for residues of the insecticide/miticide Alert [4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] as follows:

Tomatoes . . . . . 0.5 ppm

Alert is also known as Pirate, CL 303,630 or AC 303,630. A temporary tolerance has been established in/on cottonseed at 0.5 ppm. In conjunction with PP#5F04456, American Cyanamid has proposed permanent tolerances for Pirate in or on cottonseed, milk, milk fat, meat and meat by-products at 0.50, 0.01, 0.15, 0.01 and 0.10 ppm, respectively.

The proposed EUP permits the use of up to 4,990 lb ai of Alert on 4,990 acres of tomatoes in the U.S. per year over a two year period beginning in 1996. The structure of Alert is shown below:

ALERT/PIRATE



Executive Summary of Chemistry Deficiencies

- Revise label by adding minimum between-application interval and directions for the use of adjuvants and modifying the rotational crop restrictions.

CONCLUSIONS

1a. The manufacturing process and product chemistry date have undergone review by CBTS, and product chemistry data gaps have been identified which require resolution for a permanent tolerance (Memo, G. Otakie 2/18/94). Adequate product chemistry data are available for the subject EUP and temporary tolerance only.

1b. The registrant has apparently not proposed a common (ANSI) name for this chemical. CBTS would prefer that a ANSI-approved name be obtained prior to submission of the permanent tolerance request.

2. The following deficiencies in the label were noted: **a)** Based on the maximum per application and seasonal use rates, a total of five applications could be made at the maximum per application rate. The label does not specify a minimum between-application interval. Based on the submitted residue data, a spray interval of at least 7 days should be specified. **b)** There are no directions for the use of spray additives on the label. As adjuvants were not added to the finished spray in the field trial program, a restriction against their use should be added to the label. **c)** The

rotational crop restriction should be revised to specify a minimum plantback interval of 60 days for all rotational crops except those for which Alert tolerances are already established. **A revised Section B is required for this EUP.**

3a. Alert, radiochemically labelled in the aromatic ring (phenyl-UL-^{14}C) or in the pyrrole ring (pyrrole-^{14}C) was applied to tomatoes a rate of 0.2 lbs. ai/A (1X) in the field. A total of five applications were made, with the subsequent applications performed 7, 14, 21, and 28 days after the first. Tomatoes were harvested 7 and 14 days after the final application. The TRR in fruit was 0.03-0.05 ppm. The TRR was separated into two fractions: soluble and bound. The soluble fraction generally accounted for >91% of the TRR.

3b. Alert *per se* was the major component of the residue identified, accounting for 50% of the TRR at 7-days PHI and 38-50% at 14-days PHI. Unidentified peaks, none of which exceeded 0.01 ppm, accounted for up to 58% of the TRR.

3c. The nature of the residue in tomatoes is considered to be understood. Alert *per se* is the only significant component of the residue. Unchanged parent was also found to be the major component of the residue in cotton (Memo, G. Otakie 2/18/94) and oranges (Memo, G. Kramer 8/10/95).

3d. In conjunction with PP# 5F04456, CBTS will refer to the Metabolism Committee on the toxicological significance of metabolites. A decision by CBTS concerning which residues to regulate will then follow. A tolerance based on the parent only may not be appropriate; in such an instance a revised Section F and additional field studies, analytical methodology, and storage stability data may be needed.

4. As there are no animal feed items associated with tomatoes, issues pertaining to the nature and magnitude of the residue in animals are not germane to this petition.

5a. In the proposed analytical enforcement method, M 2427, tomato samples are extracted by homogenization in 15% methanol in water. After clean-up by C-18 SPE columns, the sample is analyzed using GC with ECD. The LOQ is 0.05 ppm. Acceptable recoveries were obtained at fortification levels of 0.05 and 0.50 ppm. The average recovery of Alert was 98 ± 6.5% (n=24).

5b. An ILV of this method was performed in tomatoes by Centre Analytical Laboratories. Acceptable recoveries were obtained by the laboratory. The version of this method written for citrus (M 2284) has been sent to Beltsville for PMV (Memo, G. Kramer 7/18/95). The PMV was requested for method M 2284 on oranges at 0.05, 0.25 and 0.5 ppm; and on citrus oil at 0.05, 1.0 and 2.0 ppm.

As these methods are very similar, a PMV of method M 2427 will not be required. CBTS will withhold a final conclusion on the adequacy of this method as an analytical enforcement method pending receipt of the PMV report.

5c. Pending review by FDA, the requirements for Multiresidue Testing of the parent compound have been fulfilled in conjunction with PP#5F04456 (Memo, G. Otakie, Feb. 1996).

5d. No reports on the specificity of the proposed analytical enforcement method were submitted. However, a GC/MS confirmatory method has been provided. Therefore, the specificity of method M 2427 need not be demonstrated by performing an interference study with all pesticides for which tolerances are established on tomatoes.

5e. CBTS concludes that Method M 2427 is adequate for data gathering purposes and for enforcement of the proposed temporary tolerance. A conclusion on the adequacy of the method for enforcement of the permanent tolerances will be withheld pending satisfactory method validation (PMV).

6a. Samples from the residue trials were stored for up to 14 months; and from the processing study, 12 months.

6b. Samples of tomatoes, juice and puree with fortified residues were stored frozen for up to 6 months. The average recovery in the 6-month samples, after correction for the recovery in the freshly-fortified control, was 80-96%. As these results were submitted as an interim report, details of the study procedure were not provided.

6c. For the purposes of this EUP only, the results demonstrate that residues of Alert *per se* are stable during storage in tomato commodities for up to 6 months. For the permanent tolerance petition, storage stability data must consist of a complete report and be extended to at least 14 months.

7a. A total of five tomato residue trials were conducted in 1993. These trials were located in Regions 2 (1 trial), 3 (1 trial), 5 (1 trial), 6 (1 trial) and 10 (1 trial). Alert (2SC formulation) was applied 21, 14, 7, and 0 days prior to the initial harvest at a rate of 0.2 lbs. ai/A per application (1x). Samples were harvested 0, 7, 14 and 21 days PHI. The maximum Alert residue at 0 days PHI was 0.24 ppm.

7b. The results of these trials support the proposed temporary tolerance of 0.5 ppm for Alert in tomatoes.

7c. These residue data are, however, adequate to support this EUP only. For the permanent tolerance petition, the registrant must submit the results of at least 16 tomato field trials located in

Regions 1 (1 trial), 2 (1 trial), 3 (2 trials), 5 (1 trial) and 10 (11 trials). These trials should be conducted in accordance with the *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, 6/2/94.* Data should be provided for both small (i.e., cherry) and large (i.e., beefsteak) varieties.

8a. Tomatoes for processing were grown in CA. Alert (2SC formulation) was applied 28, 21, 14, and 7 days prior to the bulk harvest at a rate of 0.5 lbs. ai/A per application (2.5x). The tomatoes were processed into juice, wet pomace, dry pomace, puree and paste. Alert residues were found to concentrate in paste (1.8X), wet pomace (63X) and dried pomace (157X).

8b. Based on the observed concentration factors, the maximum expected residue in tomato paste is 0.43 ppm, which is below the proposed tolerance for tomatoes (0.5 ppm). This value was calculated by using the highest average field trial (HAFT) value (0.24 ppm) multiplied by the concentration factor of 1.8X. Wet and dried tomato pomace are no longer considered to be a significant animal feed items (Table II, September 1995). There are thus no food/feed additive tolerances (FATs) required for this temporary tolerance petition.

8c. This processing study will be adequate to support the permanent tolerance petition, provided storage stability can be demonstrated. The need for a FAT or Section 701 Maximum Residue Limit for tomato paste will be reevaluated based on the HAFT observed in the additional residue trials.

9. There is neither a Codex proposal, nor Canadian or Mexican limits for residues of Alert in/on tomatoes. Therefore, a compatibility issue is not relevant to the proposed tolerance. A copy of the IRLS is attached to this memorandum.

RECOMMENDATIONS

CBTS will recommend in favor of the proposed temporary tolerances for Alert on tomatoes provided the registrant submits a revised Section B as detailed in conclusion 2.

A DRES run can be initiated at this time using the following residue levels:

Tomatoes (including catsup, puree, paste & juice) -- 0.50 ppm

For the permanent tolerance petition, the registrant must: **1)**

satisfactorily resolve all deficiencies in the product chemistry (conclusion 1) and analytical methodology for plants (conclusions 5b and 5e); and 2) submit an acceptable storage stability study for tomato fruit and processed commodities (conclusions 6c and 8c) and additional field residue data for tomatoes (conclusion 7c).

DETAILED CONSIDERATIONS

Product Chemistry

The manufacturing process and product chemistry date have undergone review by CBTS, and product chemistry data gaps have been identified which require resolution for a permanent tolerance (Memo, G. Otakie 2/18/94). Adequate product chemistry data are available for the subject EUP and temporary tolerance only.

The registrant has apparently not proposed a common (ANSI) name for this chemical. CBTS would prefer that a ANSI-approved name be obtained prior to submission of the permanent tolerance request.

Formulation

Alert/AC 303,630 2SC Insecticide-Miticide contains 21.44% 4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile and 78.56% inert ingredients. Alert Insecticide-Miticide contains 2.0 lbs. of active ingredient (ai) per gallon.

Proposed Use

Alert is applied when required based on scouting. The maximum application rate is 0.20 lbs. ai/A. The seasonal maximum use rate is 1.0 lbs. ai/A.

The minimum spray volume is 5 gal/acre for ground applications and 2 gal/A for aerial applications. The PHI is 0 days.

The label contains a restriction against the grazing of livestock in treated fields. The rotational crop restrictions are 60 days for small grains used for seed or feed.

The following deficiencies in the label were noted:

1) Based on the maximum per application and maximum seasonal use rates, a total of five applications could be made at the maximum per application rate. The label does not specify a minimum between-application interval. Based on the submitted residue data, a spray interval of at least 7 days should be specified.

2) There are no directions for the use of spray additives on the label. As adjuvants were not added to the finished spray in the field trial program, a restriction against their use should be added to the label.

3) The rotational crop restriction should be revised to specify a minimum plantback of 60 days for all rotational crops except those for which Alert tolerances are already established.

A new Section B is required for this EUP.

Rotational Crop Studies

The confined crop rotation study (MRID# 434928-51) indicates that residues of the parent and or metabolites CL 312094 and CL 325195 at 0.01-0.02 ppm are possible in rotated crops with a 30 day plant back interval (Memo, G. Otakie 12/8/95). However, since the study was conducted at approximately 2X the current proposed use rate of 1.0 lb ai/A/season with application made to bare ground (a worst case), at a plantback interval of 60 days or later all residue components in all rotated crops should be less than 0.01 ppm. Accordingly, at the current proposed use rate of 1.0 lb ai/A/season field rotational crop studies at are not required provided a revised label specifying a 60 day plant back interval for all rotated food/feed crops is submitted.

Nature of Residue- Tomatoes

Submitted with this petition:

> CL 303,630: Metabolism of [^{14}C] Labeled CL 303,630 in Plants Under Field Conditions. MRID# 437536-01

Note that this volume also contained a potato metabolism study (Exhibit 2, pages 261-452). As these data are not required for establishing temporary tolerances on tomatoes, this portion of the study will not be reviewed in depth at this time. A preliminary inspection of the data reveals that the TRR in tubers was <0.003

ppm and that the parent comprised 75-87% of the TRR in foliage.

In-Life Phase: Alert, radiochemically labelled in the aromatic ring (phenyl-UL-^{14}C) or in the pyrrole ring (pyrrole-^{14}C), was diluted to a specific activity of 13.63 µci/mg (phenyl) or 14.27 µci/mg (pyrrole), formulated as a suspension concentrate and applied to tomatoes a rate of 0.2 lbs. ai/A (1X) in the field. A total of five applications were made, with the subsequent applications performed 7, 14, 21, and 28 days after the first. Tomatoes were harvested 7 and 14 days after the final application.

TRR: The tissues were homogenized and the TRR was determined by combustion (Table 1). The TRR in fruit was 0.03-0.05 ppm. In foliage, the TRR was 29-31 ppm at 0-days PHI.

Table 1- TRR in tomatoes treated with phenyl- and pyrrole-labelled Alert. The PHI is calculated from the date of the final of five treatments.

PHI (Days)	TRR (ppm)	
	Phenyl	Pyrrole
7	0.04	0.03
14	0.05	0.04

Extraction and Fractionation: Tissues were homogenized and extracted sequentially with methanol/water (85:15), methanol/HCl (98:2) and acetone. The extracts were combined and concentrated. The TRR was thus separated into two fractions: soluble and bound (Table 2). The soluble fraction generally accounted for >91% of the TRR.

Table 2- Fractionation and identification of TRR in tomatoes treated with phenyl- and pyrı labelled Alert.

PHI (Days)	Label	Soluble		Bound		Residues of Alert in Soluble Fraction	
		ppm	% TRR	ppm	% TRR	ppm	% TRR
7	Phenyl	0.04	93.7	<0.01	6.3	0.02	49.8
	Pyrrole	0.03	95.7	<0.01	4.3	0.02	50.4
14	Phenyl	0.04	95.2	<0.01	4.8	0.02	37.7
	Pyrrole	0.04	91.3	<0.01	8.8	0.02	49.8

Metabolite Identification: The extracts were analyzed by two different HPLC systems and the elution profiles compared with that of reference standards (figure 1, copied from p. 8 of MRID# 437536-01). The identity of Alert was confirmed by GC/MS.

Nature of the Residue in Tomatoes: The results of HPLC fractionation of pyrrole- and phenyl-labelled tomato extracts are shown in Table 2. Alert *per se* was the major component of the residue identified, accounting for 50% of the TRR at 7-days PHI and 38-50% at 14-days PHI. Unidentified peaks, none of which exceeded 0.01 ppm, accounted for up to 58% of the TRR.

Storage Stability: The samples were stored for a maximum of 205 days prior to analysis. The HPLC profile of a tomato extract was shown to be unchanged during 454 days of storage. Storage stability is thus not an issue for this study.

Conclusions: The nature of the residue in tomatoes is considered to be understood. Alert *per se* is the only significant component of the residue. Unchanged parent was also found to be the major component of the residue in cotton (Memo, G. Otakie 2/18/94) and oranges (Memo, G. Kramer 8/10/95).

In conjunction with PP# 5F04456, CBTS will refer to the Metabolism Committee on the toxicological significance of metabolites. A decision by CBTS concerning which residues to regulate will then follow. A tolerance based on the parent only may not be appropriate; in such an instance a revised Section F and additional field studies, analytical methodology, and storage stability data may be needed.

Nature of the Residue-Animals:

As there are no animal feed items associated with tomatoes, issues pertaining to the nature of the residue in animals are not germane to this petition.

Analytical Methodology- Plants

Submitted with this petition:

CL 303,630: Laboratory Validation of GC Method M 2427 for the Determination of CL 303,630 Residues in Various Vegetables (such as Brassica, fruiting vegetables, leafy vegetablesm root and tuber vegetables and processed commodities) by Centre

Analytical Laboratories. MRID# 437536-02.

Procedure: Tomato samples (20 g) are extracted by homogenization in 15% methanol in water (300 ml). Solids are removed by filtration. After clean-up by C-18 SPE columns with hexane elution, the sample is analyzed using GC with a fused silica SPB-20 capillary column and ECD. The LOQ is 0.05 ppm for tomatoes and 0.01 ppm for tomato juice.

Results: Acceptable recoveries were obtained at fortification levels of 0.05 and 0.50 ppm. The average recovery of Alert was 98 ± 6.5% (n=24).

ILV: An ILV of this method was performed in oranges by Centre Analytical Laboratories. Acceptable recoveries were obtained by the laboratory.

PMV: The version of this method written for citrus (M 2284) has been sent to Beltsville for PMV (Memo, G. Kramer 7/18/95). The PMV was requested for method M 2284 on oranges at 0.05, 0.25 and 0.5 ppm; and on citrus oil at 0.05, 1.0 and 2.0 ppm. A validation of the confirmatory method was not requested. As these methods are, very similar, a PMV of method M 2427 will not be required. CBTS will withhold a final conclusion on the adequacy of this method as an analytical enforcement method pending receipt of the PMV report.

Multiresidue Method Testing: Pending review by FDA, the requirements for Multiresidue Testing of the parent compound have been fulfilled in conjunction with PP#5F04456 (Memo, G. Otakie, Feb. 1996).

Specificity: No reports on the specificity of the proposed analytical enforcement method were submitted. However, a GC/MS confirmatory method has been provided. Therefore, the specificity of method M 2427 need not be demonstrated by performing an interference study with all pesticides for which tolerances are established on tomatoes.

Radiovalidation: A report on radiovalidation was included in Exhibit 3 of MRID# 436221-02 (Memo, G. Kramer 8/10/95). An orange sample from the plant metabolism study (7 day PHI, pyrrole-labelled) was analyzed with the proposed enforcement method. Of the TRR, a total of 86% was extracted and the Alert residue was determined to be 0.12 ppm. These values correspond well with the extractability (85% of the TRR) and the residues identified as Alert (0.12 ppm) in the metabolism study.

Confirmatory Method: The registrant has included conditions for GC/MS analysis using a DB-5MS column and monitoring m/z 347 and 349.

Conclusions: CBTS concludes that Method M 2427 is adequate for data gathering purposes and for enforcement of the proposed temporary tolerance. A conclusion on the adequacy of the method for enforcement of the permanent tolerances will be withheld pending satisfactory method validation (PMV).

Storage Stability Studies

Samples from the residue trials were stored for up to 14 months; and from the processing study, 12 months.

Submitted with this petition:

> Interim Report: Progress of Freezer Stability Study for CL 303,630 in Various Tomato Commodities. MRID# 437536-03

Samples of tomatoes, juice and puree with fortified residues were stored frozen for up to 6 months. Details of the study procedure were not provided. Each analysis included one freshly fortified control. The average recovery in the 6-month samples, after correction for the recovery in the freshly-fortified control, was 80-96% (Table 4). For the purposes of this EUP only, the results demonstrate that residues of Alert are stable during storage in tomato commodities for up to 6 months. For the permanent tolerance petition, storage stability data must consist of a complete report and be extended to at least 14 months.

Table 3- % Recovery of Alert from RACs with fortified residues after storage.

RAC	Fortification Level (ppm)	Storage Interval (months)	Fresh Fortification Recovery (%)	Apparent Recovery in Stored Sample (%)	Corrected Recovery in Stored Sample
Tomatoes	0.50	0	94	96	102
		3	100	87	87
		6	110	88	80
Tomato Puree	0.50	0	98	99	101
		3	104	90	87
		6	98	90	92
Tomato Juice	0.50	0	105	98	93
		3	96	90	94
		6	92	88	96

Magnitude of Residue- Plants

Submitted with this petition:

CL 303,630: Residues of CL 303,360 Tomato Fruit and in Processed Tomato Commodities. MRID# 437536-04

A total of five residue trials were conducted in 1993. These trials were located in Regions 2 (1 trial), 3 (1 trial), 5 (1 trial), 6 (1 trial) and 10 (1 trial). Alert (2SC formulation) was applied 21, 14, 7, and 0 days prior to the initial harvest at a rate of 0.2 lbs. ai/A per application (1x). The spray volume was 20-46 gal/A. Samples were harvested 0, 7, 14 and 21 days PHI. Sample analysis for Alert was performed by Huntingdon Labs using the proposed enforcement method. The method was validated over a range of 0.05-0.5 ppm. The average concurrent recovery was 92.3 ± 10.0% (n=10). Analysis of the treated samples showed that the maximum Alert residue at 0 days PHI was 0.24 ppm.

Table 4- Residues in tomatoes treated with five applications of alert at a rate of 0.2 lbs. ai/A (1X).

Trial	Spray Volume (Gal/A)	PHI (Days)	Residue (ppm)
CA	20-40	0	<0.05
		3	<0.05
		7	<0.05
		14	<0.05
		21	<0.05
FL	25-46	0	<0.05
		3	<0.05
		7	<0.05
		14	<0.05
		21	<0.05
MI	20-21	0	0.24
		3	0.12
		7	0.09
		14	<0.05
		21	<0.05
NJ	24-31	0	0.16
		3	0.18
		7	0.13
		14	0.09
		21	<0.05
TX	20-35	0	<0.05
		3	<0.05
		7	<0.05
		14	<0.05
		21	<0.05

Conclusions: The results of these trials support the proposed

temporary tolerances of 0.5 ppm for Alert in tomatoes.

These residue data are, however, adequate to support this EUP only. For the permanent tolerance petition, the registrant must submit the results of at least 16 tomato field trials located in Regions 1 (1 trial), 2 (1 trial), 3 (2 trials), 5 (1 trial) and 10 (11 trials). These trials should be conducted in accordance with the *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, 6/2/94.* Data should be provided for both small (i.e., cherry) and large (i.e., beefsteak) varieties.

Magnitude of the Residue- Processed Fractions

Submitted with this petition:

> CL 303,630: Crop Residue Study: CL 303,360 Residues Processed Tomato Fruit Commodities After Multiple Applications of AC 303,630 2SC Insecticide-Miticide. Exhibit 6 of MRID# 437536-04

Tomatoes were grown in CA in 1993. Alert (2SC formulation) was applied 28, 21, 14, and 7 days prior to the bulk harvest at a rate of 0.5 lbs. ai/A per application (2.5x). The spray volume was 30-31 gal/A. A single bulk sample was harvested from the treated plot 7 days after the final application for processing at the National Food Laboratory in Dublin, CA. The tomatoes were processed into juice, wet pomace, dry pomace, puree and paste. Sample analysis for Alert was performed by Huntingdon Labs using the proposed enforcement method. The method was validated over a range of 0.05-30 ppm. The average concurrent recovery was 89 ± 10.0% (n=15). Based on the mass balance, the theoretical maximum concentration factors observed in this study were 1.2X for juice, 125X for wet pomace, 417X for dry pomace, 1.3X puree and 5X for paste. Analysis of the treated samples showed that the Alert residues concentrate in paste, wet pomace and dried pomace (Table 5).

Table 5- Results of orange processing study. The concentration factor is based on the levels found in the RAC (processor) sample.

Fraction	Residue (ppm)	Concentration Factor
RAC (Field)	<0.05	-
RAC (Processor)	0.18	-
Washed Tomatoes	0.14	0.8
Juice	0.05	0.3
Wet Pomace	11.4	63.3
Dry Pomace	28.3	157
Puree	0.17	0.9
Paste	0.32	1.8

Conclusions: Based on the observed concentration factors, the maximum expected residue in tomato paste is 0.43 ppm, which is below the proposed tolerance for tomatoes (0.5 ppm). This value was calculated by using the HAFT value (0.24 ppm) multiplied by the concentration factor of 1.8X. Wet and dried tomato pomace are no longer considered to be animal feed items (Table II, September 1995). There are thus no food/feed additive tolerances (FATs) required for this temporary tolerance petition.

This processing study will be adequate to support the permanent tolerance petition, provided storage stability can be demonstrated. The need for a FAT or Section 701 Maximum Residue Limit for tomato paste will be reevaluated based on the HAFT observed in the additional residue trials.

Magnitude of the Residue- Animals

As there are no animal feed items associated with tomatoes, issues pertaining to the magnitude of the residue in animals are not germane to this petition.

cc: PP#s 5G04574, Kramer, R.F., Circ.
RDI: M.S. Metzger (2/1/96), R.A. Loranger (1/31/96)
G.F. Kramer:804T:CM#2:(703)305-5079:7509C

_____

Page __16__ is not included in this copy.

Pages ____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

__X ___ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client communication.

_____ Claimed confidential by submitter upon submission to the Agency.

_____ Third party confidential business information.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

F. Hamed
1/16/96

Attachment: Page 1 of 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Alert/Pirate*

CODEX NO. _____

CODEX STATUS:

[M] No Codex Proposal Step 6 or Above

Residue (if Step 8): _____

PROPOSED U.S. TOLERANCES:

Petition No. 5G04574

CBTS Reviewer G.F. Kramer

Residue: parent, only

Crop(s)	Limit (mg/KG)
Tomatoes	0.5

CANADIAN LIMITS:

[M] No Canadian Limits

Residue: _____

Crop(s)	Limit (mg/KG)

MEXICAN LIMITS:

[M] No Mexican Limits (on tomato)

Residue: _____

Crop(s)	Limit (mg/KG)

NOTES

*4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile

End of Document