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

JUN 21 1993

MEMORANDUM:

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Chlorpropham. Chlorpropham Task Force Response to the Reregistration Standard: Analytical Method (MRID 42653401), Magnitude of the Residue in Postharvest Potatoes (MRIDs 42653601, 42653801, 42653901, and 42610301) Potato Processed Commodities (MRIDs 42653701, 42660201), and Storage Stability (MRID 42660101).
CBRS Nos. 11217, 11422, 11428.
DP Barcode Nos. D186971, D188291, D188292.

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In support of reregistration, the Chlorpropham Task Force, on behalf of registrants Aceto Agricultural Chemicals Corporation and Atochem North American, Inc., has submitted data on analytical method and on magnitude of the residue in potatoes treated post-harvest and potato processed commodities.

Tolerances are established for combined residues of the plant regulator and herbicide chlorpropham, isopropyl m-chlorocarbanilate (CIPC), and its metabolite 1-hydroxy-2-propyl 3'-chlorocarbanilate, calculated as CIPC, in or on potatoes (post-harvest) at 50 ppm, and soybeans at 0.2 ppm (40 CFR 180.181). Interim tolerances are established for residues of chlorpropham on numerous plant and animal commodities, pending establishment of permanent tolerances (40 CFR 180.319). Chlorpropham is a List A Chemical. A Registration Standard (Guidance Document) was issued 12/87; an Update to the Residue Chemistry Chapter was issued 10/16/91.

Conclusions

1a. For the purposes of reregistration for post-harvest uses on stored potatoes, residue data are only required for parent chlorpropham and 3-chloroaniline; data on other metabolites will not be reviewed here.

1b. Residue data are only required on the potato commodities tuber, wet peel, dry peel, granules, and chips. Data on other commodities relevant to potatoes will not be reviewed here.

1c. For validation of the analytical method, registrants should express fortification levels as ppm of sample weight.

1d. Recoveries by the analytical method of parent chlorpropham residues from fortified samples of potato commodities were acceptable.

1e. Recoveries by the analytical method of 3-chloroaniline residues from fortified samples were inadequate for nearly all potato commodities. Residue data do not provide confidence that the method could recover residues from treated samples or processed commodities, where metabolism would be more extensive and the formation of covalently-bound conjugates might occur.

1f. Judgment is reserved on submitted 3-chloroaniline residue data until the analytical methodology employed has been validated for its ability to detect conjugated 3-chloroaniline residues. Such validation can best be conducted using radiolabeled samples from metabolism studies.

2a. Residue data in the present submission were provided for potatoes given the following treatments: i) aerosol fog at 0.022 lb ai/1,000 lb potatoes, in each of two applications 90 days apart, followed by direct spray at 0.0104 lb ai/1,000 lb potatoes, or ii) aerosol fog at 0.033 lb ai/1000 lb potatoes, and a second aerosol fog 140 days later at 0.017 lb/1,000 lb potatoes. Applications at higher rates are not supported by the data provided.

2b. The highest residues in whole potatoes from any of the treatments were 24.5 ppm chlorpropham and 0.26 ppm 3-chloroaniline.

3a. Residues of parent chlorpropham do not concentrate during processing in the potato commodities granules and chips. Residues concentrate by up to 4.4X in wet peel and 11.0X in dry peel and processed potato waste during processing of treated potatoes.

3b. Judgment is reserved on 3-chloroaniline residue data (see Conclusion 1f). The data provided indicate that limits of

detection for residues of 3-chloroaniline were 0.38 ppm in potato granules and 0.45 ppm in potato chips. Data provided indicate that residues of 3-chloroaniline concentrate by up to 2.8X in wet peel and 16.2X in dry peel and processed potato waste during processing of treated potatoes.

4a. The data provided are sufficient to indicate stability of parent chlorpropham during frozen storage at -4°C for up to 183 days in wet potato peels, and up to 231 days in other potato commodities.

4b. The final report on storage stability should include data for storage periods at least as long as the maximum storage periods for corresponding samples of potato or potato processed products. Fortification levels should be expressed as ppm. Storage stability data on 3-chloroaniline, determined with an acceptable method (see Conclusion 1f), are also required.

Recommendations

The submitted studies can be upgraded to an acceptable status if additional information is provided to resolve Conclusions 1c, 1e, 1f, and 4b above. Maximum application rates on chlorpropham labels should not exceed those described in Conclusion 2a.

Additional information in response to the Conclusions may alter residue data. However, based on the data provided, maximum residues of parent chlorpropham on whole potatoes were 24.5 ppm (Conclusion 2b) and concentration factors on processed commodities were up to 4.4X in wet peel and 11.0X in dry peel. Tolerances on potato commodities should reflect the following values:
For parent chlorpropham, 30 ppm in whole potatoes, 135 ppm in wet peel, 330 ppm in dry peel, and 330 ppm in processed potato waste.

It should be noted that these values are higher than tolerances for chlorpropham that would be proposed based on data from aerosol fog application under different conditions submitted by registrant Pin Nip, Inc. (CBRS 11008, 4/16/93, J. Abbotts). However, the data submitted by registrant Pin Nip also indicated residues of 3-chloroaniline on whole potatoes of up to 0.398 ppm, a value greater than the maximum residues reported here.

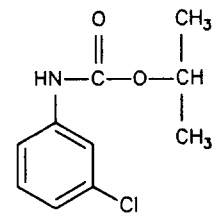
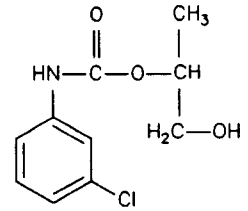
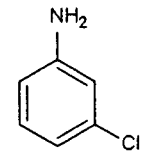
CBRS reiterates its earlier recommendations (Update to the Residue Chemistry Chapter, 10/16/91) that all tolerances not supported for reregistration be revoked. These should now include interim tolerances on spinach and carrots, unless the Agency receives formal notification from USDA or other party of an intent to support reregistration. Potential registrants should be advised that the HED Metabolism Committee's conclusions on the residues to be regulated for chlorpropham apply only to post-harvest treatment of potatoes (Memo, 3/31/93, J. Abbotts),

an additional determination of the residues to be regulated for in-field uses would be necessary, and it seems likely that residue data on additional metabolites could be required to support in-field uses.

Background

Registrants have voluntarily canceled all uses except post-harvest treatment of potatoes. The Update to the Residue Chemistry Chapter (10/16/91) concluded that data are required depicting chlorpropham residues of concern, including 3-chloroaniline, in or on potatoes analyzed immediately after treatment in commercial storage with an RTU formulation applied at the maximum registered rate as an aerosol through forced air circulation systems, and (in separate tests) with an EC formulation applied at the maximum registered rate as a dilute aqueous spray to potatoes moved along a conveyer belt. Samples from each test must be taken from several positions in the storage pile. A processing study is also required depicting chlorpropham residues of concern, including 3-chloroaniline, in potato granules, potato chips, and potato peels, wet and dried, processed from raw tubers bearing measurable, weathered residues. If residues concentrate in any of these processed commodities, the registrant must propose an appropriate food/feed additive tolerance. Structures of parent chlorpropham, the hydroxy metabolite presently included in the tolerance expression, and 3-chloroaniline are shown in Table 1.

Table 1. Chlorpropham and Metabolites.

Chemical Names (Common names)	Chemical Structure
isopropyl m-chlorocarbanilate isopropyl 3-chlorocarbanilate (chlorpropham; CIPC)	
1-hydroxy-2-propyl-3'-chlorocarbanilate (40 CFR 180.181) hydroxyisopropyl-N-(3-chlorophenyl) carbamate (isopropyl-OH-CIPC)	
3-chloroaniline (chloroaniline)	

The nature of the residue in stored potatoes treated post-harvest is adequately understood (CBRS Nos. 8942, 9137, 9166, 9171, 3/10/93, J. Abbotts). At a meeting on 3/22/93, the HED Metabolism Committee reached the following conclusions with regard to post-harvest treatment of potatoes with chlorpropham (Memo, 3/31/93, J. Abbotts):

1. The tolerance for potatoes may be continued for residues of chlorpropham only, but the need to include 3-chloroaniline in the tolerance expression will be revisited upon availability of adequate oncogenicity data.

2. Judgment is reserved on whether 3-chloroaniline is a residue of concern, and on whether concentration of 3-chloroaniline in potato processed commodities is of concern, pending the availability of data on its oncogenicity.

3. Judgment is reserved on whether concentration of chlorpropham in potato processed commodities is of concern, pending review of data on oncogenicity.

4. Judgment is reserved on the magnitude of 3-chloroaniline residues pending validation of a method adequate for detecting bound residues in potato commodities.

A submission on an analytical method (MRID 42123101) has been previously reviewed (CBRS 8942ff, 3/10/93, J. Abbotts). Review found that the method adequately recovered parent chlorpropham from fortified potato samples. However, the method was not suitable for data collection or tolerance enforcement, if residues to be regulated were to include 3-chloroaniline.

Analytical Method

In support of reregistration, the Chlorpropham Task Force submitted the following document as an addendum to the previous submission on analytical method:

Addendum 1 to Final Report (MRID No. 42123101): Analytical Method for Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham, Chlorpropham Task Force, Report No. 92CIPC01, January 26, 1993 (MRID 42653401).

This document reports that the previous method proposed gave recoveries of 3-chloroaniline and 4'-hydroxychlorpropham that were less than satisfactory in routine analysis of aged samples. The document also notes that analysis of residues can be complicated by conjugation, and a problem specific to extraction of anilines from biological systems is that a large portion of the aniline moiety is often found in bound fractions. The present submission presents a revised method for detection of parent chlorpropham, 3-chloroaniline, 4'-hydroxychlorpropham, and p-methoxychlorpropham. Matrices examined included whole potato, potato pulp, potato peels, potato chips, French fries, dehydrated granules, dried peels, and canola cooking oil.

Consistent with the conclusions of the HED Metabolism Committee (see Background section, above), the only residues of interest for the purposes of reregistration for post-harvest uses on stored potatoes are parent chlorpropham and 3-chloroaniline. Residue data on other metabolites are not required for these uses, and will not be reviewed here. In addition, Table II of the Agency's Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry, lists the potato commodities for which data are required as tuber, wet peel, dry peel, granules, chips, and potato processed waste. Feed additive tolerances for potato processed waste should be based on the maximum concentration factor observed for residues in or on granules, wet peel, or dry peel. Residue data on matrices other than those listed in Table II of Subdivision O are not required.

Conclusion 1a: For the purposes of reregistration for post-harvest uses on stored potatoes, residue data are only required for parent chlorpropham and 3-chloroaniline; data on other metabolites will not be reviewed here.

Conclusion 1b: Residue data are only required on the potato commodities tuber, wet peel, dry peel, granules, and chips. Data on other commodities relevant to potatoes will not be reviewed here.

With the revised method, the sample is homogenized in methanol:water. The homogenate is partitioned with dichloromethane and incubated in a 34°C water bath for 2 h. The mixture is filtered through glass wool and the liquid phases are allowed to separate. The dichloromethane layer is set aside and the post-extraction solids are combined with the original methanol phase. At this point a phosphate buffer saturated with NaCl (buffer pH=6.5) is added to the suspension and the mixture is sonicated for 1.5 min in short bursts. The mixture is extracted again with dichloromethane and the two dichloromethane phases are combined, concentrated by evaporation, redissolved in n-hexane, and loaded for analysis by gas chromatography with nitrogen-phosphorus detection. For samples from French fries and potato chips, oil is removed by gel permeation chromatography; the combined dichloromethane phases are concentrated, redissolved in cyclohexane:dichloromethane (1:1), and loaded onto an Enviro-beads column. The eluate is concentrated, redissolved in n-hexane, and loaded for gas chromatography. Residues are quantitated by peak area, based on calibration curves using standards. Chromatograms were provided for many samples.

Recoveries were reported for fortified samples in several potato matrices. Fortifications of samples were reported as 5.3 ng or 13.3 ng. The equivalent ppm for residues was not reported, but can be assumed based on a chart reporting the equivalent ppm represented by a limit of detection of 1 ng. For whole potato, potato pulp, potato peel, and processed wet peel, 1 ng detected represented 0.08 ppm; for granules and dried potato peel, it represented 0.38 ppm; and for potato chips, it represented 0.45 ppm. Based on these values, the fortification level of 5.3 ng can be assumed to represent a proportional ppm. Using this assumption, Table 2 summarizes method recoveries of samples fortified at 5.3 ng.

Table 2. Method Recoveries from Fortified Samples.

Commodity	Assumed Fortification Level, ppm	% Recovery, Range (Average) for Residues of:	
		Chlorpropham	3-Chloroaniline
Whole Potato	0.42	81-121 (95)	68-77 (73)
Potato Pulp	0.42	72-94 (81)	64-72 (66)
Fresh Peel	0.42	36-126 (94)	ND
Processed Wet Peel	0.42	70-113 (95)	68-89 (76)
Processed Dry Peel	2.01	66-125 (97)	49-91 (77)
Dehydrated Granules	2.01	81-102 (90)	34-89 (74)
Potato Chip	2.38	74-98 (84)	87-106 (96)

Table notes:
Fortification levels were reported as 5.3 ng; assumed ppm values are explained in the text. Six samples were analyzed for each commodity.
ND = not detected.

In addition, registrant provided "statistical control" recovery data for analysis of numerous batches of fortified samples by routine performance of the method. Fortification levels were 58.8 ng for chlorpropham and 5.32 ng for 3-chloroaniline. Average recoveries for chlorpropham for all matrices examined were acceptable; because the fortification amount was ten times that used with the samples in Table 2, these data will not be summarized. Table 3 summarizes data for 3-chloroaniline, at assumed fortification levels calculated as described for the data in Table 2:

Table 3. Routine Analysis, Recoveries from Samples Fortified with 3-Chloroaniline.

Commodity	Assumed Fortification Level, ppm	Number of Batches Analyzed	Average % Recovery
Whole Potato	0.43	35	59.6
Potato Pulp	0.43	28	54.7
Potato Peel	0.43	23	47.4
Processed Wet Peel	0.43	5	62.5
Processed Dry Peel	2.02	4	68.6
Chips with Peel	2.39	7	47.8
Chips without Peel	2.39	5	58.9
Dehydrated Granules	2.02	5	75.0

Table notes: Fortification levels were reported as 5.32 ng; assumed ppm values are explained in the text.
Duplicate samples were analyzed from each batch.

CBRS Comments, Analytical Method

The assumed ppm levels for fortified samples given in Tables 2 and 3 here were based on assumptions of sample weights relevant to the fortifications. Registrants should clarify that the ppm levels in these Tables are correct, or provide the correct information.

Conclusion 1c: For validation of the analytical method, registrants should express fortification levels as ppm of sample weight.

Recoveries of parent chlorpropham by the analytical method were acceptable for both the limited fortified samples (Table 2), and the "statistical control" analysis of many batches. Recoveries of 3-chloroaniline from fortified samples were inadequate for fresh peel for the limited samples (Table 2), and were outside the range of acceptable values for nearly all potato commodities in the "statistical control" analysis.

Conclusion 1d: Recoveries by the analytical method of parent chlorpropham residues from fortified samples of potato commodities were acceptable.

Conclusion 1e: Recoveries by the analytical method of 3-chloroaniline residues from fortified samples were inadequate for nearly all potato commodities.

The Residue Chemistry Chapter (8/14/87) concluded that data collection and enforcement methodology should include hydrolysis step(s) in order to detect free and conjugated side-chain modified metabolites, such as isopropyl-OH-CIPC and 3-chloroaniline. The Guidance Document (12/87) specified that methods used for data collection, including methods specific for 3-chloroaniline, be tested with regard to their efficiency in extracting bound residues. To this end, it was recommended that methods be validated with weathered radioactive residues in conjunction with the required metabolism studies.

The Update to the Residue Chemistry Chapter (10/16/91) reiterated the requirement that methods must include a hydrolysis step at the tissue stage to release bound/conjugated residues. Such a hydrolysis step must be incorporated into all methods to be used for data collection in support of tolerances. The efficiency of extraction of bound/conjugated residues must be determined for any or all residue data collection methods the registrant has used or will use to support tolerances. This may best be conducted with samples containing radiolabeled material from plant and animal metabolism studies.

The nature of the residue in potatoes treated post-harvest is adequately understood (CBRS Nos. 8942ff, 3/10/93, J. Abbotts). Residues identified in peel included 3-chloroaniline, representing 0.35% of TRR (0.102 ppm). Also identified was 3-chloroaniline-N-glucosylamine, present at 0.05% TRR in peel, and 0.18% in pulp, for a combined level of 0.23% TRR (0.067 ppm). Conjugated forms of 3-chloroaniline may thus be present in potatoes and potato processed commodities. It was this observation that led the HED Metabolism Committee to conclude that judgement was reserved on the magnitude of 3-chloroaniline residues pending validation of a method adequate for detecting bound residues in potato commodities (Memo, 3/31/93, J. Abbotts).

In the present submission (MRID 42653401), the performing laboratory discussed reports indicating that 3-chloroaniline can form conjugates or bind with matrix. Yet the analytical method used in the present submission extracts tissues with methanol:water. These extraction conditions would not be expected to release conjugated 3-chloroaniline for subsequent identification. It should be noted that Tables 2 and 3 indicate inadequate recovery by the method from fortified samples, where 3-chloroaniline may be bound to matrices. These data do not provide confidence that the method could recover residues from treated samples or processed commodities, where metabolism would be more extensive and the formation of covalently-bound conjugates might occur. Consistent with the conclusions of the HED Metabolism Committee (Memo, 3/31/93, J. Abbotts), judgment must therefore be reserved on 3-chloroaniline residue data until the analytical methodology employed has been validated for its ability to detect conjugated 3-chloroaniline residues.

Conclusion 1f: Judgment is reserved on submitted 3-chloroaniline residue data until the analytical methodology employed has been validated for its ability to detect conjugated 3-chloroaniline residues. Such validation can best be conducted using radiolabeled samples from metabolism studies.

Magnitude of the Residue

In support of reregistration, the Chlorpropham Task Force provided the following documents as part of the present submission:

Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for the Fresh Market, Chlorpropham Task Force, Report No. 92CIPC04, January 26, 1993 (MRID 42653601).

Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for Processing into Potato Chips, Chlorpropham Task Force, Report No. 92CIPC06, January 26, 1993 (MRID 42653801).

Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for Processing into Frozen or Dehydrated Products, Chlorpropham Task Force, Report No. 92CIPC05, January 26, 1993 (MRID 42653901).

In-Life Phase Study: Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham, Chlorpropham Task Force, Report No. 92CIPC02, November 16, 1992 (MRID 42610301).

Protocol. The last document above, MRID 42610301, describes the protocol followed for the magnitude of the residue trials. The University of Idaho surveyed commercial operators for potato storage and treatment patterns and concluded that potatoes stored for fresh market use could receive two aerosol fogging treatments, if stored for more than 8 mo, plus a direct spray prior to shipment. Potatoes stored for processing other than chips could receive two aerosol fogging treatments; potatoes stored for processing into chips could receive a single fogging treatment, or a second fogging treatment under some circumstances. The treatments followed in residue trials were designed to reflect these different treatment combinations.

Tests were carried out at the University of Idaho facility in Kimberly, ID. The test commodity was Russet Burbank white potatoes produced by a local grower. Potatoes were stored in each of 5 bin/fumigation chambers, which were isolated from each other. Each bin is 12 ft x 20 ft by 27 ft high. The bins consist of concrete floors with air supply ducts in the floors, and plywood insulated walls covered with galvanized steel. Two sampling pipes, 42 in by 18 ft, were used for sampling the potato

pile. The pipes were placed in each bin prior to loading it with potatoes; each pipe contained sampling ports at 1, 8, and 15 ft above the air ducts of the bin floor. Bins were filled with potatoes to a height of approximately 16 ft; each bin contained approximately 140,000 lb potatoes.

Products used in the test were Decco 273 Aerosol (EPA Reg. No. 2792-41), 4.3 lb ai/gal; Sprout Nip 4A Aerosol (EPA Reg. No. 2749-264-34704), 4.0 lb ai/gal; and Decco 276 EC (EPA Reg. No. 2792-40), 2 lb ai/gal. Potatoes sampled from Bins 2 and 3 were treated by direct spray with the Decco EC formulation at 1 lb ai/960 cwt (96,000 lb), or 0.0104 lb ai/1,000 lb potatoes. The same bins were treated by fog with the Decco Aerosol formulation at 1 lb ai/455 cwt (45,500 lb), or 0.022 lb ai/1,000 lb potatoes, two times at 90 days apart. Potatoes from these bins were then treated by direct spray. Bins 2 and 3 represented potatoes intended for fresh market, or for processing into frozen and dehydrated products. Accordingly, some of these potatoes were shipped for processing.

Bins 4 and 5 were treated by fog with the Sprout Nip Aerosol formulation at 1 lb ai/300 cwt (30,000 lb), or 0.033 lb ai/1000 lb potatoes, followed after 140 days by a second aerosol fog treatment at 1 lb ai/600 cwt (60,000 lb), or 0.017 lb/1,000 lb potatoes. These treatments are allowed for Section 24(c) registrations for potatoes intended for processing into chips, and some of these potatoes were shipped for processing. Bin 1 contained untreated control potatoes, isolated from the other bins.

Aerosol application was through a portable fogger, which forced the fog into the sealed storage bin at the bottom of the pile through floor vents. For 24 h after application, the bin was sealed and no fresh air entered the system. Following treatment the bins were exhausted for 24 h and then aerated for another 24 h with fresh air to allow a safe atmosphere for workers to collect samples. For application by direct spray, tubers were collected from each of three sampling depths at specified times in the study. The tubers were washed in water and allowed to air dry until damp. Rotten tubers were discarded, and the remaining tubers were weighed, to calculate the amount of formulation to apply for a rate of 1 lb ai per 96,000 lb potatoes. Application was by direct spray of a 1% aqueous emulsion to tubers moving along a conveyor line.

Tuber samples were collected before aerosol application, 48 h after aerosol application, and at the end of the storage season. Samples were taken within the pile at 1, 8, and 15 ft above the air ducts. Samples were taken from the untreated bin before sampling any treated bins. Collected tubers were placed in a wire basket lined with a disposable plastic garbage bag that was changed between each sample. Tubers were placed in plastic-

laminated cloth sample bags, which were tied shut and identified. Sample bags were placed in insulated cardboard shipping boxes. Boxes were shipped on the same day as sampling, or stored in a cooler at 40°F. Freezing the samples was not practicable because peeling and other processing of the samples at the analytical laboratory or processing plant was necessary. United Parcel Service provided two-day delivery to a UPS facility in Pullman, WA, where representatives of the University of Idaho took custody of the boxes.

Conclusion 2a: Residue data in the present submission were provided for potatoes given the following treatments: i) aerosol fog at 0.022 lb ai/1,000 lb potatoes, in each of two applications 90 days apart, followed by direct spray at 0.0104 lb ai/1,000 lb potatoes, or ii) aerosol fog at 0.033 lb ai/1000 lb potatoes, and a second aerosol fog 140 days later at 0.017 lb/1,000 lb potatoes. Applications at higher rates are not supported by the data provided.

Residue Data. Potato samples received by the University of Idaho were analyzed by the method described above (Addendum 1, MRID 42653401). Whole, pulp, and potato peel samples were prepared, homogenized, and frozen until the date of extraction. Limits of detection were 0.08 ppm for these matrices for each of chlorpropham and 3-chloroaniline. Representative chromatograms were provided.

Document MRID 42653601, listed above, provided data on the samples representing potatoes intended for fresh harvest; these were the samples in Bins 2 and 3 treated twice by aerosol and once by spray. Samples were collected at days 0, 5, 91, 96, 140, and 215, where aerosol fog treatment occurred on days 1 and 92. Samples were homogenized and frozen within 2 weeks of receipt by the performing laboratory. However, analysis in some cases did not occur until 13 months after homogenization. Composite samples of 2 potatoes treated by aerosol and 4 potatoes treated by aerosol and/or spray were prepared by homogenization. After receipt by the performing laboratory, the samples were frozen at approximately -20°C. The performing laboratory provided storage stability data on parent chlorpropham (see below), and indicated that an additional storage stability study on metabolites, including 3-chloroaniline, would be completed in November 1993.

Residue data were reported for whole potato, peel, and pulp. Wet peel and dry peel are potato processed commodities, and data from the processing study (see below) should allow a calculation of whether residues concentrate in peel during processing. Only data for whole potato samples are summarized here. Data are reported for parent and 3-chloroaniline; as indicated in Conclusion 1f, judgment is reserved on the submitted 3-chloroaniline residue data until the analytical method has been validated for its ability to detect conjugated residues.

Chlorpropham residues in whole potatoes showed initial increases following each fog treatment, and then little decline of residues with time; 3-chloroaniline residues in whole potatoes showed initial increases following each fog, then modest increases with time of storage. For samples that had been treated by fog, residues in samples taken from the bottom of the pile were modestly higher than in samples from the middle or top. Residues on control, untreated samples were ≤ 0.08 ppm of either compound. Table 4 summarizes residue data for whole potatoes, treated by up to two fog applications, followed by one direct spray application:

Table 4. Residues in Whole Potatoes Treated by Fog and/or Spray.

Treatment	Day of Sample	Chlorpropham, ppm, Range (Average)	3-Chloroaniline, ppm, Range (Average)
Spray only	0	2.73-4.33 (3.56)	≤0.08
	5	4.28-8.15 (5.78)	≤0.08
One fog + Spray	5	4.83-11.2 (7.60)	≤0.08-0.09 (≤0.08)
	91	6.10-9.38 (8.04)	0.09-0.12 (0.10)
Two fog + Spray	96	5.95-13.5 (9.13)	≤0.08-0.16 (0.12)
	140	7.46-12.7 (10.5)	0.10-0.13 (0.12)
	215	7.05-10.5 (8.17)	0.12-0.15 (0.14)

Table notes: Applications were aerosol fog at 1 lb ai/455 cwt, on days 1 and 92, and/or direct spray at 1 lb ai/960 cwt on the day of sampling.

Document MRID 42653901, listed above, provided data on the samples representing potatoes intended for processing into frozen or dehydrated products; these were the samples in Bins 2 and 3 treated twice by aerosol, but not treated by direct spray. These potatoes were therefore treated in a manner similar to the samples intended to represent fresh harvest potatoes (Table 4), except no direct spray was applied. Samples were collected at days 0, 5, 91, 96, 140, and 215, where aerosol fog treatment occurred on days 1 and 92. Samples were homogenized and frozen within 2 weeks of receipt by the performing laboratory. However, analysis in some cases did not occur until 10 months after homogenization. Other procedures were the same as for the samples in Bins 2 and 3 described above. Chlorpropham residues in whole potatoes showed initial increases following each fog treatment, then modest decline of residues with time. 3-Chloroaniline residues showed initial increases following each fog treatment, then modest declines with time. As with the study summarized in Table 4, residues in samples taken from the bottom of the pile were modestly higher than residues in samples taken from the middle or top. Table 5 summarizes data for whole potatoes, treated twice in 90 days by aerosol fog:

Table 5. Residues in Whole Potatoes Treated by Fog, Twice in 90 Days.

Treatment	Day of Sample	Chlorpropham, ppm, Range (Average)	3-Chloroaniline, ppm, Range (Average)
One fog	5	2.82-9.21 (6.15)	≤0.08-0.21 (0.14)
	91	1.24-8.46 (4.05)	0.11-0.19 (0.13)
Two fog	96	4.32-16.6 (9.20)	≤0.08-0.20 (0.12)
	140	4.21-24.5 (9.35)	≤0.08-0.14 (0.09)
	215	5.26-11.3 (7.71)	≤0.08-0.09 (0.08)

Table notes: Applications were aerosol fog at 1 lb ai/455 cwt, on days 1 and 92.

Document MRID 42653801, listed above, provided data on the samples representing potatoes intended for processing into potato chips; these were the samples in Bins 4 and 5 treated twice by aerosol, at two different rates, 140 days apart. Samples were collected at days 0, 5, 91, 140, 145, and 215, where aerosol fog treatment occurred on days 1 and 141. Samples were homogenized and frozen within 2 weeks of receipt by the performing laboratory. However, analysis in some cases did not occur until 12 months after homogenization. Other procedures were the same as for the samples in Bins 2 and 3 described above, but with no direct spray application. Chlorpropham residues in whole potatoes showed initial increases following each fog treatment, then modest declines with time. 3-Chloroaniline residues showed initial increases following each fog treatment, then modest fluctuations with time. As with the studies above, residues in samples taken from the bottom of the pile were modestly higher than residues in samples taken from the middle or top. Table 6 summarizes data for whole potatoes, treated twice in 140 days by aerosol fog:

Table 6. Residues in Whole Potatoes Treated by Fog, Twice in 140 Days.

Treatment	Day of Sample	Chlorpropham, ppm, Range (Average)	3-Chloroaniline, ppm, Range (Average)
One fog	5	4.33-24.0 (12.0)	0.09-0.25 (0.14)
	91	2.98-15.6 (8.02)	≤0.08-0.17 (0.11)
	140	5.71-13.8 (9.99)	0.13-0.26 (0.20)
Two fog	145	5.40-17.4 (11.6)	0.16-0.25 (0.20)
	215	6.12-16.7 (8.91)	≤0.08-0.13 (0.10)

Table notes: Applications were aerosol fog at 1 lb ai/300 cwt on day 1, followed by 1 lb ai/600 cwt on day 141.

Conclusion 2b: The highest residues in whole potatoes from any of the treatments were 24.5 ppm chlorpropham and 0.26 ppm 3-chloroaniline.

Processing Study

In support of reregistration, the Chlorpropham Task Force has provided the following documents as part of the present submission:

Processing of Stored Potatoes Treated Postharvest with Chlorpropham to Determine Magnitude of Residues in Processed Potato Fractions, Department of Food Science and Human Nutrition, Chlorpropham Task Force, Report No. 92CIPC03, January 7, 1993 (MRID 42653701).

Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Processed Potato Products and Peels, Chlorpropham Task Force, Report No. 92CIPC07, February 2, 1993 (MRID 42660201).

Document MRID 42653701 describes the protocol used for processing treated potatoes. As indicated above under the Magnitude of the Residue section, treated tubers were placed into boxes. Boxes were shipped on the same day as sampling, or stored in a cooler at 40°F. United Parcel Service provided two-day delivery to a UPS facility in Pullman, WA, where representatives of the University of Idaho took custody of the boxes. Samples were then delivered to the processing pilot plant at Washington State University, Pullman, WA. Samples were stored at 38°F prior to processing. Processed potato commodities were stored at 38°F until transport to the University of Idaho Analytical Laboratory for residue analysis. Processed potato mash samples were frozen at -35°F and transported in dry ice to Englar and Associates, Moses Lake, WA, where samples were dried to potato granules. Dry potato granule samples were transported in dry ice from Englar and Associates to Washington State, then stored at -35°F until

shipment to the University of Idaho for residue analysis. Sample histories were provided for each sample.

Potato samples were collected as described in the Magnitude of the Residue section from Bins 2 and 3 for processing into granules, and from Bins 4 and 5 for processing into chips. On each collection day, samples of twelve potatoes were taken; from these, composite samples of three each were taken for processing into chips with peel and chips without peel (Bins 4 and 5), and into wet peels, dry peels, and granules (Bins 2 and 3); samples were also processed into French fries with and without peel. Processing of potatoes followed commercial practices as closely as possible. Potatoes were steamed to simulate commercial peeling, but then were peeled by hand because of the small sample size and to obtain sufficient quantities for analysis. Potato peel drying is not a commercial process, but was included in the protocol. Commercial potato chip processing includes a water wash for starch removal. The protocol did not include this wash, increasing the potential recovery of residues in chips. The protocol also did not include salting the chips.

Document MRID 42660201, listed above, reported residues in processed potato commodities, including french fries and canola oil. As indicated in Conclusion 1b, only data on the processed commodities wet peel, dry peel, granules, and chips will be reviewed here. Limits of detection were reported as 0.08 ppm for wet peel, 0.38 ppm for dried peel and dehydrated granules, and 0.45 ppm for chips with and without peel. Residues were reported for duplicate samples of potatoes collected from the top, middle, or bottom of each bin. Residues were undetectable in processed commodities of untreated potatoes. This document did not report residues in tuber samples, but these can be obtained from MRIDs 42653801 and 42653901, described above. Table 7 summarizes data for residues of chlorpropham in processed potato commodities and corresponding whole potato samples; Table 8 summarizes data for residues of 3-chloroaniline:

Table 7. Chlorpropham Residues in Potato Processed Commodities.

Sample Day	Location	Range of Residues (Average), ppm, in:						
		Bins 2 and 3:				Bins 4 and 5:		
		Whole Potatoes	Wet Peel	Dry Peel	Granules	Whole Potatoes	Chips With Peel	Chips Without Peel
5	Bottom	6.60-9.21 (8.18)	10.8-13.5 (12.4)	58.8-89.9 (67.2)	≤0.38	13.0-24.0 (18.3)	2.71-3.62 (3.25)	≤0.45
	Middle	2.82-8.22 (5.18)	8.84-12.5 (10.0)	32.3-75.9 (53.4)	≤0.38	4.27-14.4 (9.59)	1.31-1.59 (1.45)	≤0.45
	Top	2.93-7.30 (4.95)	6.98-10.1 (8.54)	28.5-60.0 (41.0)	≤0.38	4.33-10.7 (8.19)	0.70-1.84 (1.24)	≤0.45
91	Bottom	2.40-5.54 (4.12)	7.30-10.2 (9.26)	26.2-47.3 (39.4)	0.77-0.78	6.57-12.1 (8.44)	3.96-6.41 (5.28)	≤0.45
	Middle	1.87-6.06 (4.12)	7.20-9.75 (8.74)	29.6-51.9 (39.9)	0.47-0.79	3.81-15.6 (9.33)	2.83-4.95 (4.05)	≤0.45
	Top	1.24-8.46 (3.91)	3.39-10.9 (7.01)	20.2-55.9 (43.0)	0.72-0.84	2.98-9.29 (6.15)	2.32-4.93 (3.67)	≤0.45
96	Bottom	8.09-16.6 (11.4)	31.3-34.2 (33.1)	75.5-145 (97.8)	0.57-1.19			
	Middle	5.63-10.1 (8.06)	13.6-32.4 (23.3)	65.4-106 (80.7)	≤0.38-0.71			
	Top	4.32-12.3 (8.18)	14.3-32.9 (23.0)	44.0-102 (71.8)	≤0.38-0.75			
140	Bottom	6.15-24.5 (11.7)	25.8-45.4 (36.7)	56.6-63.3 (60.2)	0.67-0.87	7.18-13.8 (10.7)	3.66-4.47 (3.97)	≤0.45
	Middle	6.15-12.5 (10.0)	25.9-41.9 (33.4)	41.5-78.1 (59.3)	0.63-0.96	9.52-12.4 (10.9)	1.97-4.16 (3.51)	≤0.45
	Top	4.21-9.45 (6.33)	16.5-42.5 (27.7)	29.7-76.7 (55.5)	0.69-0.82	5.71-10.8 (8.36)	2.35-7.93 (4.83)	≤0.45
145	Bottom					10.2-17.4 (13.2)	0.82-4.35 (2.73)	≤0.45
	Middle					10.8-17.3 (13.2)	1.70-8.41 (4.01)	≤0.45
	Top					5.40-12.0 (8.43)	1.19-4.07 (2.26)	≤0.45
215	Bottom	6.94-9.41 (7.91)	11.2-14.4 (12.6)	25.2-58.9 (41.5)	0.91-1.50	7.40-10.5 (8.73)	3.75-7.03 (5.26)	1.19-1.64
	Middle	6.31-11.3 (8.15)	10.3-14.6 (13.4)	24.1-56.9 (39.6)	1.32-2.10	7.68-16.7 (10.6)	4.53-7.91 (6.26)	1.09-1.76
	Top	5.26-8.23 (7.06)	14.9-17.3 (16.1)	25.2-56.5 (38.9)	1.08-1.55	6.12-10.6 (8.47)	4.56-7.05 (5.66)	1.33-1.53

Table 8. 3-Chloroaniline Residues in Potato Processed Commodities.

Sample Day	Location	Range of Residues (Average), ppm, in:						
		Bins 2 and 3:				Bins 4 and 5:		
		Whole Potatoes	Wet Peel	Dry Peel	Granules	Whole Potatoes	Chips With Peel	Chips Without Peel
5	Bottom	≤0.08-0.21 (0.14)	0.12-0.18 (0.16)	≤0.38-2.71 (1.11)	≤0.38	0.15-0.25 (0.19)	≤0.45	≤0.45
	Middle	≤0.08-0.20 (0.14)	0.08-0.16 (0.12)	≤0.38-1.03 (0.57)	≤0.38	0.09-0.15 (0.12)	≤0.45	≤0.45
	Top	≤0.08-0.19 (0.14)	≤0.08-0.12 (0.10)	≤0.38-2.20 (0.84)	≤0.38	0.09-0.21 (0.12)	≤0.45	≤0.45
91	Bottom	0.12-0.16 (0.14)	0.08-0.18 (0.14)	0.48-0.84 (0.68)	≤0.38	≤0.08-0.15 (0.11)	≤0.45	≤0.45
	Middle	0.12-0.15 (0.13)	≤0.08-0.12 (0.10)	0.40-0.58 (0.51)	≤0.38	≤0.08-0.16 (0.12)	≤0.45	≤0.45
	Top	0.11-0.19 (0.14)	≤0.08-0.16 (0.11)	0.42-0.68 (0.56)	≤0.38	≤0.08-0.17 (0.12)	≤0.45	≤0.45
96	Bottom	≤0.08-0.20 (0.13)	0.25-0.39 (0.31)	1.58-3.46 (2.10)	≤0.38			
	Middle	≤0.08-0.15 (0.11)	0.13-0.29 (0.20)	1.00-1.28 (1.17)	≤0.38			
	Top	≤0.08-0.15 (0.11)	0.11-0.24 (0.17)	≤0.38-1.06 (0.78)	≤0.38			
140	Bottom	0.08-0.14 (0.11)	0.23-0.36 (0.31)	0.38 (0.38)	≤0.38	0.16-0.26 (0.21)	≤0.45	≤0.45
	Middle	≤0.08-0.11 (0.09)	0.23-0.27 (0.25)	0.38-0.53 (0.42)	≤0.38	0.13-0.25 (0.19)	≤0.45	≤0.45
	Top	0.08-0.09 (0.09)	0.18-0.30 (0.25)	0.38-0.53 (0.44)	≤0.38	0.13-0.23 (0.18)	≤0.45	≤0.45
145	Bottom					0.17-0.25 (0.21)	≤0.45	≤0.45
	Middle					0.17-0.24 (0.20)	≤0.45	≤0.45
	Top					0.16-0.20 (0.18)	≤0.45	≤0.45
215	Bottom	≤0.08-0.09 (0.08)	0.19-0.22 (0.20)	0.93-1.47 (1.20)	≤0.38	0.08-0.13 (0.11)	≤0.45	≤0.45
	Middle	≤0.08-0.08 (0.08)	0.16-0.21 (0.18)	1.07-1.14 (1.10)	≤0.38	≤0.08-0.13 (0.10)	≤0.45	≤0.45
	Top	≤0.08	0.21-0.24 (0.22)	0.92-1.61 (1.26)	≤0.38	≤0.08-0.13 (0.10)	≤0.45	≤0.45

Notes to Tables 7 and 8:
Samples in Bins 2 and 3 were treated twice by fog, 90 days apart (Table 5); samples in Bins 4 and 5 were treated twice by fog, 140 days apart (Table 6).
For whole potatoes, averages for each location are of eight samples, four from each bin. For processed commodities, averages are of four samples, two from each bin. Averages were not calculated when residues on all samples were nondetectable or inspection indicated that concentration did not occur.

Inspection of the data in Table 7 indicates that residues of chlorpropham do not concentrate in granules or chips without peel; for these commodities, the maximum residues are always lower than the maximum residues in or on corresponding whole potato samples. Residues of chlorpropham also do not concentrate in chips with peel; averaged residues and maximum residues are always lower than the same values in or on corresponding whole potatoes. The data in Table 7 do indicate that chlorpropham residues consistently concentrate in wet peel and dry peel. In Table 8, residues of 3-chloroaniline were nondetectable in all samples of granules and chips with and without peel. However, the limits of detection, 0.38 ppm for granules and 0.45 ppm for chips, were larger than the maximum residues of 3-chloroaniline detected on whole potatoes (0.26 ppm). If 3-chloroaniline is ultimately included in the tolerance expression, the limits of detection on processed potato commodities will have to be recognized. The data in Table 8 also indicate that residues of 3-chloroaniline concentrate in wet peel and dry peel. Table 9 summarizes the concentration factors, based on the averaged data in Tables 7 and 8, for parent and 3-chloroaniline in wet and dry peel:

Table 9. Concentration Factors for Chlorpropham Residues.

Sample Day	Location	Concentration Factors for Residues of:			
		Chlorpropham in:		3-Chloroaniline in:	
		Wet Peel	Dry Peel	Wet Peel	Dry Peel
5	Bottom	1.5	8.2	1.1	7.9
	Middle	1.9	10.3	0.9	4.1
	Top	1.7	8.3	0.7	6.0
91	Bottom	2.2	9.6	1.0	4.9
	Middle	2.1	9.7	0.8	3.9
	Top	1.8	11.0	0.8	4.0
96	Bottom	2.9	8.6	2.4	16.2
	Middle	2.9	10.0	1.8	10.6
	Top	2.8	8.8	1.5	7.1
140	Bottom	3.1	5.1	2.8	3.5
	Middle	3.3	5.9	2.8	4.7
	Top	4.4	8.8	2.8	4.9
215	Bottom	1.6	5.2	2.5	15.0
	Middle	1.6	4.9	2.2	13.8
	Top	2.3	5.5	2.8	15.8

Table notes: Concentration factors are based on the averaged residue values for wet peel, dry peel, and corresponding whole potatoes, in Tables 7 and 8.

In Table 9, maximum concentration factors for chloropropham residues are 4.4 in wet peel and 11.0 in dry peel. Applying these values to the maximum chlorpropham residues in whole potatoes, 24.5 ppm, gives values of 108 ppm in wet peel and 270 ppm in dry peel; these values are greater than the highest single values reported for the respective commodities in Table 7. Maximum concentration factors for 3-chloroaniline are 2.8 in wet peel and 16.2 in dry peel. Applying these values to the maximum 3-chloroaniline residues in whole potatoes, 0.26 ppm, gives values of 0.73 ppm in wet peel and 4.2 ppm in dry peel; these values are greater than the highest single values reported for the respective commodities in Table 8. Feed additive tolerances for processed potato waste should be based on the maximum concentration factor observed for residues in or on granules, wet peel, or dry peel; these factors are then 11.0 for parent chlorpropham and 16.2 for 3-chloroaniline, both equivalent to the concentration factors for dry peel.

Conclusion 3a: Residues of parent chlorpropham do not concentrate during processing in the potato commodities granules

and chips. Residues concentrate by up to 4.4X in wet peel and 11.0X in dry peel and processed potato waste during processing of treated potatoes.

Conclusion 3b: Judgment is reserved on 3-chloroaniline residue data (see Conclusion 1f). Data provided indicate that limits of detection for residues of 3-chloroaniline were 0.38 ppm in potato granules and 0.45 ppm in potato chips. Data provided indicate that residues of 3-chloroaniline concentrate by up to 2.8X in wet peel and 16.2X in dry peel and processed potato waste during processing of treated potatoes.

Storage Stability Data

In support of reregistration and the residue data in the present submission, the Chlorpropham Task Force provided the following document as part of the present submission:

Determination of Storage Stability of Field-Incurred Residues of Chlorpropham and Metabolites of Concern in or on Fresh, Stored and Processed Potatoes, Chlorpropham Task Force, Report No. 92CIPC08, February 2, 1993 (MRID 42660101).

Storage stability of chlorpropham residues were reported in whole potato, potato pulp, fresh potato peel, French fries with skins, potato chips with skins, granules, processed wet peels, and processed dried peels. Samples were prepared from treated whole potatoes, and samples of each matrix were stored frozen at -4° to -6°C. Data were reported for storage of up to 231 days. Registrant indicated that additional data would be forthcoming and an additional storage stability study including metabolites was in progress, scheduled for completion in November 1993.

In accordance with Conclusion 1b above, data will be reviewed only for the commodities whole potato, chips, granules, and processed wet peels and dried peels. Method recoveries on the day of analysis were determined with samples fortified with 58.7 ng chlorpropham. The ppm value of this amount was not provided, but based on other data, can be assumed to represent the following for specified matrices: 4.7 ppm in whole potato and processed wet peel, 22.3 ppm in granules and processed dried peel. Potato chips were fortified with 19.6 ng chlorpropham, which is assumed to represent 8.82 ppm. Table 10 summarizes storage stability data. Data are presented for the shortest and longest storage times reported; if results at the longest time point seemed questionable, data for shorter storage times are presented:

Table 10. Storage Stability Data for Parent Chlorpropham.

Commodity	Days in Storage	Residue, ppm	Fresh Fortification Recovery	Apparent Recovery in Stored Sample, %	Corrected Recovery in Stored Sample, %
Whole Potato	9	10.6	110		
	218	5.73	59.9	54.1	99.4
Potato Chips	20	4.58	82.0		
	231	3.41	68.4	74.5	89.3
Granules	5	1.82	61.0		
	209	2.29	88.2	125	93.6
Processed Dry Peels	6	87.9	82.0		
	62	93.8	71.5	107	122
	96	58.4	94.2	66.4	59.0
	120	48.7	83.1	55.4	54.7
	153	154	79.2	175	181
	180	137	73.4	156	174
	210	104	63.6	118	153
Processed Wet Peels	9	32.8	71.0		
	183	27.3	66.1	83.2	89.4
	217	3.67	82.9	11.2	9.6

Table notes:
Residue data represent the average of two samples or two determinations. Recoveries are calculated using the data for the shortest storage time as a baseline.

Recoveries at the longest storage time reported are acceptable for whole potato, granules, and chips. Recoveries were highly variable for dry peels, but the data indicate no major loss of residues in this matrix. Recoveries were clearly unacceptable for processed wet peels at 217 days of storage, but were acceptable at 183 days.

It should be noted that these times do not represent the maximum storage times for samples in the accompanying residue and processsing studies. As indicated above, the time between sample collection and analysis was as long as 13 months for whole potatoes, 12 months for potato chips, and 10 months for wet peel, dry peel, and granules. The final report on storage stability should include data for storage periods at least as long as the maximum storage periods for corresponding samples of potato or potato processed products.

Conclusion 4a: The data provided are sufficient to indicate stability of parent chlorpropham during frozen storage at -4°C for up to 183 days in wet potato peels, and up to 231 days in other potato commodities.

Conclusion 4b: The final report on storage stability should include data for storage periods at least as long as the maximum storage periods for corresponding samples of potato or potato processed products. Fortification levels should be expressed as ppm. Storage stability data on 3-chloroaniline, determined with an acceptable method (see Conclusion 1f), are also required.

Recommendation: The submitted studies can be upgraded to an acceptable status if additional information is provided to resolve Conclusions 1c, 1e, 1f, and 4b above. Consistent with Conclusion 2a, registrations not supported by the data submitted or other registrants should be canceled.

Review of Protocol

CBRS previously reviewed a protocol for these studies submitted by the Chlorpropham Task Force (CBRS No. 8580, 9/18/91, R.B. Perfetti). That review found the protocol acceptable, with the following comments: 1) The study should utilize the maximum number of treatments and rates as well as the worst case types of applications. 2) Details of sample histories should be carefully recorded. 3) Consideration should be given to sample storage with respect to storage stability. 4) All samples should be analyzed for the total terminal residue of concern. 5) The registrant is directed to the Guidance Document regarding potato processing fractions to be analyzed.

In conducting the studies in the present submission, registrant has either complied with these comments, or deficiencies have been identified in the Conclusions above.

Previous Data

Data separately submitted by another registrant, Pin Nip, Inc., in support of aerosol fog application under slightly different conditions have previously been reviewed (CBRS No. 11008, 4/16/93, J. Abbotts). Deficiencies must be resolved for those data as well, but they indicated that tolerances on potato commodities should reflect values for parent chlorpropham of 12 ppm in whole potatoes and 140 ppm in dry peel. If data from both sets of registrants are accepted, the data from the Chlorpropham Task Force indicate higher tolerances are appropriate. The data from Pin Nip, based on a different analytical method, indicated residues of 3-chloroaniline on whole potatoes of up to 0.398 ppm, which is higher than the residues reported here.

Recommendations: Additional information in response to the Conclusions may alter residue data. However, based on the data provided, maximum residues of parent chlorpropham on whole potatoes were 24.5 ppm (Conclusion 2b) and concentration factors on processed commodities were up to 4.4X in wet peel and 11.0X in dry peel. Tolerances on potato commodities should reflect the following values:
For parent chlorpropham, 30 ppm in whole potatoes, 135 ppm in wet peel, 330 ppm in dry peel, and 330 ppm in processed potato waste.

It should be noted that these values are higher than tolerances for chlorpropham that would be proposed based on data from aerosol fog application under different conditions submitted by registrant Pin Nip, Inc. (CBRS 11008, 4/16/93, J. Abbotts). However, the data submitted by registrant Pin Nip also indicated residues of 3-chloroaniline on whole potatoes of up to 0.398 ppm, a value greater than the maximum residues reported here.

Additional Crops

According to the Update to the Residue Chemistry Chapter (10/16/91), registrants have voluntarily canceled all uses except post-harvest treatment of stored potatoes. The Update recommended that tolerances for uses not supported for reregistration be revoked, with the exception of interim tolerances on spinach and carrots. The Update recommended that in view of an existing use on spinach under SLN No. VA910004, and an indication from USDA that it wished to support uses on spinach and carrots, the interim tolerances for spinach and carrots should remain in effect until appropriate permanent tolerances were established.

A representative of USDA has now indicated that because of resource limitations, USDA does not plan to support reregistration of chlorpropham on spinach and carrots (CBTS No. 11846, 5/24/93, M.F. Flood; and James Parochetti, USDA, personal communication, 6/9/93). The recommendation that all tolerances not supported for reregistration be revoked should now include interim tolerances on spinach and carrots, unless the Agency receives formal notification from USDA or other party of an intent to support reregistration. Present registration of spinach and carrots represent in-field uses, and the HED Metabolism Committee's conclusions on the residues to be regulated for chlorpropham apply only to post-harvest treatment of potatoes (Memo, 3/31/93, J. Abbotts). Potential registrants should be advised that an additional determination by the HED Metabolism Committee would be necessary for the residues to be regulated for in-field uses, and it is likely that residue data on additional metabolites could be required.

Recommendation: CBRS reiterates its earlier recommendations (Update to the Residue Chemistry Chapter, 10/16/91) that all

tolerances not supported for reregistration be revoked. These should now include interim tolerances on spinach and carrots, unless the Agency receives formal notification from USDA or other party of an intent to support reregistration. Potential registrants should be advised that the HED Metabolism Committee's conclusions on the residues to be regulated for chlorpropham apply only to post-harvest treatment of potatoes (Memo, 3/31/93, J. Abbotts), an additional determination of the residues to be regulated for in-field uses would be necessary, and it seems likely that residue data on additional metabolites could be required to support in-field uses.

cc:Circ, Abbotts, RF, Chlorpropham List A File, SF
RDI:FBSuhre:6/17/93:MSMetzger:6/18/93:EZager:6/21/93
H7509C:CBII-RS:JAbbotts:Rm805A:305-6230:6/21/93
[redacted]JA6:chlorpro.9

CHLORPROPHAM (CASE 0271/CODE 108301)
UNOFFICIAL RESIDUE CHEMISTRY DATA SUMMARY THROUGH 4/16/93[1]

REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH CODEX[2]

Guideline Number and Topic[3]	Phase 5 data requirements satisfied?	MRID(s)[4]
171-3 Directions for use	No	
171-4(a) Plant Metabolism	Yes[5]	42085601
171-4(b) Animal Metabolism	No[6]	42112201,42130401
171-4(c) Residue Analytical Methods - Plants	No[7]	42123101
171-4(d) Residue Analytical Methods - Animals	Reserved	
171-4(e) Storage Stability	No	
171-4(k) Crop Field Trials		
171-4(k) Root and Tuber Vegetables Group		
Carrots	No[8]	
Potatoes	No[9]	42566801
(Processed food/feed)	No[10]	42566801
Sugar beets [see 171-4(l)]	No	
171-4(k) Leaves of Root and Tuber Vegetables		
Sugar beet tops	No	
171-4(k) Bulb Vegetables Group		
Garlic	No	
Onions (green and dry bulb)	No	
171-4(k) Leafy Vegetables (except Brassica)		
Spinach	No[8]	
171-4(k) Legume Vegetables (succulent/dried)		
Beans (succulent and dried)	No	
Peas (succulent and dried)	No	
Soybeans [see 171-4(l)]	No	
171-4(k) Foliage of Legume Vegetables		
Bean vines and hay	No	
Pea vines and straw	No	
Soybean forage and hay	No	
171-4(k) Fruiting Vegetables Group		
Tomatoes [see 171-4(l)]	No	
171-4(k) Small Fruits and Berries Group		
Blackberries	No	
Blueberries	No	
Cranberries	No	
Raspberries	No	
171-4(k) Cereal Grains Group		
Rice [see 171-4(l)]	No	
171-4(k) Forage, Fodder, and Straw of Cereal Grains		
Rice straw	No	

CHLORPROPHAM (CASE 0271/CODE 108301) UNOFFICIAL RESIDUE CHEMISTRY DATA SUMMARY THROUGH 4/16/93[1] REASSESSMENT OF U.S. TOLERANCES AND POTENTIAL FOR HARMONIZATION WITH CODEX[2]		
Guideline Number and Topic[3]	**Phase 5 data requirements satisfied?**	**MRID(s)[4]**
171-4(k) Grass Forage, Fodder, and Hay Group		
Grass forage and hay	No	
171-4(k) Non-grass Animal Feeds		
Alfalfa [see 171-4(l)]	No	
Clover	No	
Trefoil	No	
171-4(k) Miscellaneous Commodities		
Safflower [see 171-4(l)]	No	
Tobacco	No	
171-4(j) Meat/Milk/Poultry/Eggs	No[11]	
171-4(f) Potable Water	Yes	
171-4(g) Fish	Yes	
171-4(h) Irrigated Crops	N/A	
171-4(i) Food Handling Establishments	N/A	
171-5 Reduction of Residues	N/A	
171-6 Tolerances	No[12]	

[1]Registration Standard issued 12/87. Reregistration Standard Update to the Residue Chemistry Chapter issued 10/16/91. This summary is unofficial and subject to correction.

[2]No Codex MRLs are established or proposed for chlorpropham.

[3]N/A = Guideline requirement not applicable.

[4]MRIDs that were reviewed in the current submission are designated in shaded type.

[5]CBRS 8942, 9137, 9166, 9171, 3/10/93, J. Abbotts: The nature of the residue in stored potatoes treated post-harvest is adequately understood.
Memo, 3/31/93, J. Abbotts: The HED Metabolism Committee reached the following conclusions with regard to post-harvest treatment of potatoes with chlorpropham: 1) The tolerance may be continued for residues of parent only, but the need to include 3-chloroaniline in the tolerance expression will be revisited upon availability of adequate oncogenicity data. 2) Judgment is reserved on whether 3-chloroaniline is a residue of concern, and on whether its concentration in potato processed commodities is of concern, pending availability of data on its oncogenicity. 3) Judgment is reserved on whether concentration of chlorpropham in potato processed commodities is of concern, pending review of data on oncogenicity. 4) Judgment is reserved on the magnitude of 3-chloroaniline residues pending validation of a method adequate for detecting bound residues in potato commodities.

[6]CBRS 8942ff, 3/10/93, J. Abbotts: Additional work is necessary to upgrade the ruminant metabolism study; 80% of the extracted residue in liver was not identified. Considering that potato commodities

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are not significant feed items, the poultry metabolism study is adequate, provided adequate storage stability data are submitted.

[7]CBRS 8942ff, 3/10/93, J. Abbotts: The submitted method adequately recovers parent and other metabolites from fortified potato samples. The method is not adequate for 3-chloroaniline, and an improved method will be necessary if this or additional metabolites are designated residues to be regulated. Validation of the method for recovery of free and conjugated residues of concern remains an outstanding requirement. Enforcement methods must be validated by an independent laboratory.

[8]Update: In view of existing use on spinach permitted under SLN VA910004 and USDA's wish to support use on carrots and spinach, interim tolerances for carrots and spinach should remain in effect until appropriate permanent tolerances are established. A full complement of residue data is necessary to establish tolerances.

[9]CBRS 8580, 9/18/91, R. Perfetti: A protocol for the 4 lb formulation was accepted.
CBRS 9013, 12/26/91, P. Deschamp: CBRS advised SRRD that data from residue tests in which warehouse-stored potatoes were treated with a 4 lb formulation as a fog would support registration of a 7 lb formulation, provided that the 4 lb and 7 lb formulations are identical types (e.g., both are RTU formulations), have the same application rate and timing, and that the prescribed methods of application are essentially identical. At the present time, products registered for postharvest use on potatoes include the 49.65% and 78.5% ready-to-use (RTU); 25, 36, and 46.5% emulsifiable concentrate (EC), and 46% soluble concentrate/liquid (SC/L) formulations.
CBRS 9278, 4/17/92, S. Funk: A protocol for the 7 lb formulation was acceptable with revisions.
CBRS 11008, 4/16/93, J. Abbotts: The submitted study can be upgraded to an acceptable status if additional information is provided. Judgment is reserved on 3-chloroaniline residue data until the analytical method has been validated for its ability to detect conjugated 3-chloroaniline residues. The data were submitted to support use of an RTU formulation applied by aerosol/fogger at 0.017 lb ai/1000 lb potatoes. Registrations with higher rates, different application methods, or other formulations not supported by other registrants should be canceled.

[10]CBRS 11008, 4/16/93, J. Abbotts: The submitted study can be upgraded to an acceptable status if additional information is provided. Judgment is reserved on 3-chloroaniline residue data until the analytical method has been validated for its ability to detect conjugated 3-chloroaniline residues.

[11]CBRS 8942ff, 3/10/93, J. Abbotts: A ruminant feeding study is required, to be conducted after the nature of the residue in ruminants is adequately understood and residues to be regulated in animal commodities have been determined.

[12]Update: Registrant voluntarily canceled all uses except post-harvest treatment of potatoes. The permanent tolerance on soybeans and all interim tolerances on commodities not supported for reregistration should be revoked.

cc: Abbotts; Chlorpropham Reregistration Standard File; Lois Rossi, SRRD
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