Reading 5-21-86

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 21 1986

MEMORANDUM

SUBJECT: Response (1/14/86) by Shell Development Co. to the data gaps identified in the Product Chemistry Chapter and Residue Chemistry Chapter of the 9/85 Monocrotophos Registration Standard. (RCB #471) Accession No. 260813

FROM: Cynthia Deyrup, Ph.D., Chemist
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TO: Amy Rispin, Chief
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and

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Background

In response to the data gaps cited in the Monocrotophos Registration Standard (9/85), Shell has submitted an octanol/water partition coefficient study and a list of the residue chemistry data gaps cited in the Monocrotophos Registration Standard along with Shell's responses to these data gaps. The data gaps cited in the Registration Standard will be restated below followed by Shell's Response and RCB's Comments/Conclusions.

§ 158.120 Product Chemistry

63-11 Octanol/Water Coefficient

Shell's Response

The registrant has submitted an octanol/water partition coefficient study, which had been reviewed previously and found to be adequate [memo of S. Malak; octanol/water partition coefficient for monocrotophos (Azodrin) ground water data call-in, 10/31/84]. Octanol saturated water solutions of monocrotophos (0.005 M to 0.05 M; 5 and 10 ml) were partitioned with 35-40 ml of octanol. The monocrotophos concentrations in the phases were determined by reversed phase HPLC. Sample chromatograms were submitted. The following partition coefficient values were reported.

Molarity	% Recovery	K_{ow}
0.050	104	0.69
0.025	103	0.70
0.010	102	0.68
0.005	101	0.71

RCB's Comments/Conclusions

The submitted study is adequate; data gap 63-11 has been fulfilled.

§ 158.125 Residue Chemistry

171-2: Chemical Identity: The same chemical identity data as required under § 158.120 are required, with emphasis on impurities that would constitute a residue problem.

Shell's Response

Shell intends to provide the data; no submission date was given.

RCB's Comments/Conclusions

The data have not yet been submitted. RCB notes that the due date for data gap 171-2 is March, 1986. This data gap is still outstanding. The Registrant should be reminded that his submission is overdue.

171-3: Directions for Use: Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

Shell's Response

Shell intends to provide the data; no submission date was given.

RCB's Comments/Conclusions

The data have not yet been submitted. RCB notes that the due date for data gap 171-3 is March, 1986. This data gap is still outstanding. The Registrant should be reminded that his submission is overdue.

171-4: Nature of the Residue (Metabolism)

Plants

The following additional data are required:

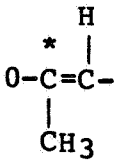
- Residues of [^{32}P] or [^{14}C] monocrotophos must be characterized and quantified in or on cottonseed produced from seed treated with 25 lb a.i./ton of delinted seed. Exaggerated rates may be necessary to obtain sufficient activity for identification

- Residues of [^{32}P] or [^{14}C] monocrotophos must be characterized and quantified in or on peanuts grown in soil treated twice at 1 lb a.i./A; peanuts must be harvested 15 days after the final application. Exaggerated rates may be necessary to obtain sufficient activity for characterization. The residue data must also include residues for the trimethyl phosphate contaminant.

- In addition the Office of the Assistant Administrator has requested that the residue data show evidence regarding the fate and stability of trimethyl phosphate (TMP) in plants.

- Crop field trials should not be started until the plant metabolism study has been completed.

NOTE: Labeling should take place at carbon atom with asterisk:



Shell's Response

Shell does not intend to support the cottonseed treatment use pattern. The registration for cottonseed treatment is not Shell's.

Shell proposes to conduct a study with ^{14}C-monocrotophos fortified with 1% TMP on cotton after foliar application. This study is aimed at studying the storage stability of monocrotophos/TMP on foliage and at determining the magnitude of total ^{14}C-residues in cottonseed.

Shell intends to carry out the ^{14}C-monocrotophos peanut metabolism study reflecting soil application.

RCB's Comments/Conclusions

Note to PM: The holder of the registration for the use of monocrotophos on cottonseed (seed treatment) should be notified because this data gap needs to be fulfilled.

The cottonseed study as described is not a metabolism study but will be done in addition to the required metabolism study on peanuts. According to the Registrant, the purpose of this study is to investigate the storage stability of Azodrin/TMP on foliage. A cottonseed metabolism study reflecting foliar application was not required by the Registration Standard. The question of the storage stability of Azodrin and TMP is discussed further under the relevant section, 171-4: Storage Stability Data.

Since the Office of the Assistant Administrator has requested information on the fate (metabolism) and stability (persistence) of TMP in plants, radiolabeled TMP, in addition to radiolabeled monocrotophos, will have to be used in the peanut metabolism study. This study, which involves soil application, would also address RCB's concerns regarding the potential for uptake of soil metabolites following foliar application.

Since the plant metabolism data have not yet been received, this data gap, 171-4, plant metabolism, is still outstanding, but not overdue at this time.

171-4 Nature of the Residue (Metabolism)

Livestock

The following additional data are required:

- Metabolism studies utilizing ruminants. Animals must be dosed for 3 days with either [^{32}P] or [^{14}C] monocrotophos at a concentration in the total diet which will result in sufficient residues in the milk, liver, muscle and fat for characterization. Animals must be sacrificed within 24 hours of the final dose (milk must be collected twice daily).

- Metabolism studies utilizing poultry. Animals must be dosed 3 days with either [^{32}P] or [^{14}C] monocrotophos at a concentration in the total diet which will result in sufficient residues in the eggs, liver, kidney, fat, and muscle for characterization. Eggs must be sampled twice daily throughout the treatment period. Animals must be sacrificed within 24 hours of the final dose. If poultry

metabolism is found to differ significantly from that of ruminants, then nonruminant (swine) data will be required (i.e., in the absence of rat metabolism data). If poultry and ruminant metabolism differ from that in the rat, then additional swine data are required. (Note: the type of labeling should be the same for both animal and plant metabolism studies.)

Shell's Response

Shell will consider conducting a ruminant and poultry metabolism study after the plant metabolism studies define the level of dietary exposure to livestock. If the metabolism and residue data indicate that dietary exposure will not be a problem, Shell will request a waiver from the livestock metabolism requirements. Shell requests a deferral of the livestock metabolism studies until the requisite data can be generated and reviewed.

In the meantime, Shell will be submitting a metabolism study for monocrotophos in the cow and goat in the near future.

RCB's Comments/Conclusions

Although Shell may request a deferral of the livestock metabolism studies, it also stated that it will be submitting a cow and goat metabolism study "in the near future." The registrant will need to clarify this.

Moreover, RCB notes that Shell's petition for a tolerance of 2.0 ppm Azodrin on corn fodder and forage is pending. Since livestock metabolism will probably need to be delineated before this tolerance can be established, it seems unlikely that a waiver of any livestock metabolism studies would be appropriate. However, regarding animal metabolism studies, RCB advises that the studies reflect the feeding of a single compound (usually parent), not a mixture of compounds. If a significant component of the residue in/on feed is a metabolite, then additional animal metabolism studies involving dosing with the metabolite may be required, especially if the plant metabolite is not an animal metabolite. Therefore, RCB recommends that animal metabolism studies involving Azodrin should be conducted without delay. This data gap, 171-4: animal metabolism, is not yet fulfilled.

171-4 Storage Stability

Since most of the residue data submitted provide no information as to storage interval or conditions prior to analysis, the following information is required:

- Details must be provided as to the conditions and length of storage of samples of peanuts, peanut hulls, and sugarcane from which data were generated in support of established tolerances. If any storage interval

was >8 months, stability data reflecting that storage interval must be submitted, and residue data submitted in support of the tolerance in question must be corrected for degradation of residues in storage; this may result in reevaluation of established tolerances. This same requirement would apply to any future applications to reinstate the tomato and/or potato use.

It is recommended that samples from which any data required in this Standard are generated be stored frozen for no more than 8 months prior to analysis.

The nature of the residue in plants is not adequately understood. If the requested data indicate additional residues of toxicological concern, data reflecting the stability of such residues in frozen storage may be required.

Shell's Response

Sugarcane

Shell has provided the dates upon which cane samples were shipped to the analytical laboratory and states that the cane was stored frozen until analyzed. The storage periods and conditions were given for the sugarcane field trials submitted with PP #0F0912.

RCB's Comments/Conclusions

From the harvest dates provided in the original petition (PP #0F0912), RCB estimates that all the cane sampls were stored frozen for periods ranging from 3 1/2 - 6 months. The data gap regarding the storage periods and conditions of the sugarcane field samples has been fulfilled.

Shell's Response

Peanuts

Shell has provided the dates upon which peanut samples were placed into storage and the analysis dates. The residue data generated by these peanut samples were submitted with PP #3F1348.

RCB's Comments/Conclusions

The dates upon which the peanut samples were put into storage (according to Shell's present submittal) coincide with the shipping dates reported in PP #3F1348. The data sheets submitted for these trials state that the peanuts were harvested, frozen, and then shipped to the laboratory. From the sampling dates given on these data sheets, RCB estimates that the storage periods from sampling to analysis ranged from 3 months to 14.5 months. Of the 8 field trials, only 2 trials involved storage periods of <8 months. The data presented in the Registration Standard indicate that the half life of

monocrotophos could be as short as 15 months in storage. RCB arrived at this figure by extrapolating the decay curve generated by the data from the cottonseed storage stability study which was cited in the Standard. The cottonseed study was an 8 month study. The same half life was calculated from using the data in this study to determine a decay constant (assuming a first order rate of decay) and then using the decay constant to calculate the half life. The registrant has not submitted storage stability data to support the residue data; he has only described storage conditions.

The available residue data indicate that the current monocrotophos tolerances on peanuts (0.05 ppm) and on peanut hulls (0.5 ppm) may be exceeded after Azodrin application according to the registered use. In Reference TIR-24-166-70, it was reported that a peanut hull sample after treatment with Azodrin at a 2 X application rate exhibited an Azodrin residue level of 0.45 ppm 15 days after treatment (registered PHI, 15 days). A second peanut hull sample exhibited an Azodrin residue level of 0.26 ppm after treatment with Azodrin at a 1 X application rate. However, these samples had been stored 13.5 months. If the half life for residues of Azodrin on peanuts is assumed to be 15 months, the Azodrin levels in these samples could exceed the registered tolerance of 0.5 ppm on peanut hulls.

In Reference TIR-24-168, it was reported that a peanut sample which had been treated at a 1 X application rate exhibited an Azodrin residue level of 0.04 ppm 22 days after treatment (registered PHI, 15 days). This sample had been stored 14.5 months before analysis. Again, translation of the storage stability data available on cottonseed to peanuts would lead to the conclusion that the tolerance of 0.05 ppm on peanuts is inadequate.

However, RCB considers it inappropriate to translate storage stability data from a short term study (i.e., the cottonseed study), in which the data were generated by an undescribed method, to the peanut samples, which were stored up to 14.5 months. Since the registrant has not submitted storage stability data to cover the necessary time frame, this data gap is still outstanding.

RCB's Comments/Conclusions re: Storage stability of TMP

The Office of the Assis tant Administrator has requested data to determine whether measurable residues of TMP result in or on raw agricultural commodities and processed food/feed from the maximum registered use of monocrotophos. Appropriate storage stability data on TMP will therefore be needed to support the requested residue data.

171-4 Magnitude of the Residue-Residue Studies for each Food Use

The Office of the Assistant Administrator has requested data to determine whether actual measurable residues of trimethyl phosphate (TMP) result in or on raw agricultural commodities and processed foods/feed from the maximum registered use of monocrotophos.

Root and Tuber Vegetables

Potatoes; potatoes (processed)

Shell's Response

Shell has deleted potatoes from all end use labels.

RCB's Comments/Conclusions

The requirement for residue data reflecting analyses for TMP in/on potatoes is no longer necessary, since the Registrant has removed potatoes from his end use labels. Note to PM: The revised end use labels should be checked to ensure that potatoes are no longer listed as a crop for treatment with Azodrin. This data gap has been eliminated, provided that Shell has deleted potatoes from all end-use labels.

Fruiting Vegetables (Except cucurbits)

Tomatoes; tomatoes (processed)

The Office of the Assistant Administrator has requested TMP residue data on tomatoes and processed commodities derived from tomatoes (tomato puree, catsup, and dry pomace).

Any future application to reinstate the tomato use must include a processing study of tomatoes bearing measurable weathered residues of monocrotophos to determine if food/feed additive tolerances are required on tomato puree, catsup, and dry pomace.

Shell's Response

Shell did not mention the registered use of monocrotophos on tomatoes in their submission. According to Gary Otakie (private communication), RD, Shell wants to delete tomatoes from all end use labels.

However, Shell has submitted residue data on tomato leaves reflecting analyses for TMP. Tomatoes received one application at a rate of 1 lb. a.i./A. The leaves were sampled with a leaf punch gun at 0 hr, 2 hr, 4 hr, 8 hr, 24 hr, 48 hr, and 120 hrs. See the Cottonseed section, that follows in this review for a description of the methodology.

The following levels of Azodrin and TMP on tomato leaves were reported.

Sample	PHI (hours)	Azodrin (ppm)	TMP (ppm)
Leaves after Triton rinse	0	6.0-9.8	0.02-0.04
	2	5.4-6.8	0.03-0.04
	4	6.8-7.2	0.03-0.04
	8	4.2-5.9	<0.01
	24	7.1-8.4	<0.01
	48	4.7-6.8	<0.01
	120	1.7-1.8	<0.01
Triton rinse	0	48-67	0.08-0.10
	2	38-66	0.05
	4	47-49	0.02
	8	55-67	0.03
	24	51-53	<0.01

RCB's Comments/Conclusions

The submitted residue data indicate that residue levels of TMP would not be detectable on tomato leaves 48 hours after treatment.

Note to PM and the Registrant:

The revised end use labels should be checked to verify whether tomatoes are no longer listed as a crop for treatment with Azodrin; RCB needs copies of any revised labels for its files for future reference. If tomatoes are no longer on the end-use labels, this data gap is moot. However, in view of Shell's response to data gap 171-5: Reduction of Residue, the registrant should be reminded that before the use on tomatoes can be reinstated, the data gaps regarding tomato processing will have to be fulfilled. As requested by the Office of the Assistant Administrator, TMP residue data on tomatoes and processed commodities would also need to be submitted.

Miscellaneous Commodities

Cottonseed

Inadequate processing studies were submitted. Therefore the

following additional data are required:

- Residues of monocrotophos must be determined in meal, hulls, soapstock, crude oil, and refined oil processed from cottonseed bearing measurable weathered residues. It may be necessary to apply exaggerated rates to obtain detectable residues in the raw agricultural commodity. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

Also, the Office of the Assistant Administrator has requested TMP residue data to determine whether measurable residues of TMP result in cottonseed and its processed food/feed items from the maximum registered use of monocrotophos on cotton.

Shell's Response

Shell has submitted residue data reflecting analyses for TMP on cotton leaves from a cotton field trial conducted in CA.

Azodrin is registered for use on cotton at rates of up to 1 lb. a.i./A. There is no limit on the number of applications permitted; the treatment interval is 5-7 days, and a 21 day PHI is in effect. There is a label restriction against allowing livestock to graze on treated fields or feeding treated gin trash to livestock. (Although there is no limit to the number of Azodrin applications permitted on cotton, RCB notes that residue data reviewed in the Registration Standard reflected up to 20 applications.)

Cotton Field Trial Protocol

Azodrin 5 containing 0.8% TMP was applied with ground equipment to mature cotton at a rate of 1 lb. a.i./A. One application was made; PHI's of 0, 1, 2, and 5 days were observed. Samples were not frozen until arrival at the laboratory 0-5 days after sampling.

TMP Analytical Methodology

Leaf discs (collected with a leaf punch gun) were rinsed with an aqueous Triton X-100 solution, then were homogenized in the presence of chloroform and sodium sulfate. The solids remaining after filtration were extracted 2 more times with chloroform. The Triton rinses were extracted with chloroform. The chloroform extracts were cleaned up by column chromatography on Florisil.

Residues of TMP were determined by GLC with flame photometric detection. The limit of detection for TMP was 0.01 ppm. Recoveries dislodgable residues of TMP from the Triton rinse of cotton leaves fortified at 0.07-0.14 ppm ranged from 76-92%. Recoveries of TMP from the discs after rinsing ranged from 70-73% at the same fortification level. Representative chromatograms of check, fortified, and treated samples of cotton leaf were submitted. RCB concludes that the method-

ology used to generate the residue data is adequate.

Residue Data

The residue levels of Azodrin and TMP in/on cotton leaves are given below.

Sample	PHI (days)	Azodrin (ppm)	TMP (ppm)
Leaves after Triton rinse	0	3.9-8.8	0.10-0.27
	1	2.4-4.1	0.06-0.09
	2	2.4-8.1	0.02-0.09
	5	1.3-2.6	<0.01
Triton rinse	0	54-111	0.10-0.24
	1	15-23	0.08-0.11
	2	9.6-9.9	0.03-0.10
	5	2.7-5.3	<0.01-0.01

PHI	Total TMP Residues in Cotton Leaves (Triton rinse + leaves after Triton rinse; ppm)
0	0.20-0.51
1	0.14-0.20
2	0.19-0.05
5	<0.01-0.01

Shell intends to provide data on cottonseed processing.

RCB's Comments/Conclusions

Only one application was made in this field trial, although the number of applications permitted to cotton is without limit. The submitted residue data indicate that 5 days after a single application, TMP residues have dissipated to about 0.01 ppm. The submitted residue data reflect analyses of leaves, not cottonseed. The Office of the Assistant Administrator had requested residue data on TMP in/on the raw agricultural commodity cottonseed and the food/feed commodities derived from cottonseed. Therefore, RCB concludes that the above submitted residue data on leaves have not fulfilled the data gap on the need for residue data reflecting determinations of TMP in cottonseed and cottonseed fractions from cotton treated at the maximum registered use of Azodrin.

Furthermore, the cottonseed processing study has not yet been received. This data gap is still outstanding.

Peanuts

A decision as to the adequacy of the established tolerance for residues in or on peanuts must be postponed pending receipt of the data requested below regarding analytical methods used to generate residue values. In addition, an inadequate processing study was submitted. Therefore, the following additional data are required:

- A description of the analytical method(s) used to generate the data contained in the following reports must be submitted: TIR-24-124-70, TIR-24-143-70, TIR-24-166-70, TIR-24168-70, TIR-24-100-71.

- Data for residues in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. It may be necessary to apply exaggerated rates to obtain detectable residues in the raw agricultural commodity. If residues concentrate in any of these processed products, appropriate food/feed tolerances must be proposed.

Also, the Office of the Assisstant Administrator has requested TMP residue data on peanuts and the food/feed commodities derived from peanuts.

Shell's Response

Shell intends to carry out a peanut processing study.

Method PMS-G-918/69 was used to determine Azodrin in peanuts.

Shell has submitted residue data reflecting analyses for TMP on peanuts.

Azodrin is registered for use on peanuts at a rate of 1 lb. a.i./A. A PHI of 15 days is in effect. Two applications per growing season are permitted. There is a label restriction against feeding treated vines or hay to livestock or allowing livestock to graze in treated fields.

Shell has submitted residue data on peanuts from 2 field trials conducted in NC and GA. Peanuts received 2-3 applications of Azodrin at a rate of 1 lb. a.i./A. PHI's of 14 and 21 days were observed. Samples arrived frozen at the lab; analyses of the samples took place about one month after arrival at the laboratory.

The method used to determine residue levels of TMP was described above for the cotton study, although the peanuts were not subjected to the Triton rinse.

Recoveries of TMP from peanuts fortified with 0.1 ppm TMP ranged from 64-78%.

Representative chromatograms of check, treated, and fortified samples of peanuts were submitted.

Residues of TMP were undetectable in all peanut samples (<0.01 ppm). Residue levels of Azodrin ranged from <0.02-0.03 ppm.

No TMP residue data on peanut hulls were submitted.

RCB's Comments/Conclusions

The results of the peanut processing study have not yet been received. This data gap is not yet fulfilled.

Method PMS-G-918/69 is Method A in PAM, Vol. II. This data gap is fulfilled.

RCB considers the method used to determine levels of TMP in peanuts to be adequate. The data indicate that levels of TMP in peanuts treated according to the registered use are less than 0.01 ppm. This data gap is fulfilled.

The available storage stability data do not permit RCB to judge whether the established tolerances of 0.5 ppm monocrotophos on peanut hulls and 0.05 ppm on peanuts are adequate; in fact, the available data indicate that both tolerances may be inadequate (see RCB's Comments/Conclusions under 171-4: Storage Stability Data).

The Office of the Assistant Administrator has requested TMP residue data on peanut hulls/peanut fractions; however, these data have not yet been submitted. This data gap is not yet fulfilled.

Sugarcane

Inadequate sugarcane processing studies were submitted. In addition, because sugarcane forage is a raw agricultural commodity used for animal feed, a tolerance proposal and a pregrazing interval proposal are required; alternatively, feeding and grazing restrictions may be proposed. The following additional data are required:

- Data reflecting residues in molasses, refined sugar, and bagasse processed from sugarcane bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

- Data reflecting residues in or on sugarcane forage at intervals following the last of several (>5)aerial foliar applications of the 5 lb/gal SC/L formulation. Tests must be conducted in FL (42%), LA (24%), and TX (4%); percent contribution to 1982 sugarcane crop

appears in parentheses (Agricultural Statistics, 1983, p. 82, preliminary 1982 figures). The treatment rate in FL and LA must be 0.75 lb. a.i./A/application and in TX must be 1 lb. a.i./A/application. A pregrazing interval must be proposed. Alternatively, feeding and grazing restrictions may be proposed.

Also, the Office of the Assistant Administrator has requested TMP residue data on sugarcane and food/feed items derived from sugarcane.

Shell's Response

Shell has not submitted residue data on sugarcane reflecting TMP analyses.

Shell states that it will submit a sugarcane processing study.

The problem of possible residues of Azodrin on sugarcane forage was not addressed.

A TX state label permits use of the 5 lb/gal SC/L formulation on sugarcane at a rate of 1 lb. a.i./A. This formulation may only be applied aerially to sugarcane. There is no limit on the number of applications permitted. A PHI of 30 days is in effect.

Shell has submitted residue data from 2 sugarcane field trials conducted in TX. In one trial, sugarcane received 5 aerial applications of Azodrin at a rate of 1 lb. a.i./A. The treatment intervals ranged from 12-24 days. In the second trial, sugarcane received 6, 20, or 31 weekly aerial applications of Azodrin. PHI's of 30 days were observed in both field trials. Azodrin 5 WMI or Azodrin 5 WM was used in the trials. Samples were stored 9-10 months before analysis for residues of Azodrin. Method MMS-R504-1, which is very similar to Method A in PAM, Vol. II, was used to determine Azodrin residues. Representative chromatograms of check, treated, and fortified samples of sugarcane were submitted. The submitted chromatograms support the claimed limit of detection of 0.02 ppm Azodrin. Residue levels of Azodrin in the first trial were <0.02 ppm; in the second trial, residue levels of Azodrin ranged from 0.03 ppm (20-31 applications) to 0.04 ppm (6 applications).

RCB's Comments/Conclusions

The registrant has not submitted any residue data on sugarcane reflecting analyses for TMP, as requested by the Office of the Assistant Administrator. This data gap is not yet resolved.

Shell has not yet submitted the results of the sugarcane processing study; this data gap is not yet resolved.

Shell did not respond to the data gap involving sugarcane forage.

The submitted sugarcane residue data appear to reflect analyses on sugarcane. According to the description of field processing, stalks were cut at the base, topped, and leaves were stripped. The Registration Standard had requested residue data on sugarcane forage, or, alternatively, feeding and grazing restrictions in a revised label. This data gap is not yet fulfilled.

SLN or 24(c) Uses: Swiss Chard, Corn (seed), Deciduous Fruit and Nut Trees, Bermuda Grass Grown for Seed

The Office of the Assistant Administrator has requested TMP residue data on raw agricultural commodities treated at the maximum registered rates to determine whether measurable levels of TMP would result from these treatments.

Shell's Response

These uses are not registered by Shell. Shell does not intend to submit data to support these uses.

RCB's Comments/Conclusions

Note to PM: The holders of the registered SLN or 24 (c) uses should be notified because this data gap needs to be resolved.

Intrastate Uses: Nonbearing Citrus

The Office of the Assistant Administrator has requested data to determine whether measurable residues of TMP result from the registered use.

Shell's Response

Shell requests a waiver of this requirement on the basis that treatment is to young citrus trees that are not bearing fruit; therefore residue data are not required.

RCB's Comments/Conclusions

At this time, RCB does not recommend for a waiver of this requirement. The residue of interest must be shown to be non-persistent and non-systemic. Therefore, RCB will require at least limited TMP residue data reflecting treatment of non-bearing citrus trees. This data gap is not resolved.

171-5: Reduction of Residue

Reduction of residue data are required when the assumption of tolerance level residue results in an unsafe level of exposure. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. Any request to reinstate the tomato use must include residue reduction data for raw and processed tomatoes in order to estimate actual dietary exposure from residues of monocrotophos.

The data must include residue reduction levels as the raw tomatoes pass through the marketplace and are sold as fresh tomatoes or used in the manufacture of processed tomato products. Also, data on residue reduction levels from processing tomatoes must include data before and after washing, soaking, and canning. Cooking and canning water should also be analyzed. Residue detection levels should reflect those obtainable using GC/mass spectroscopy.

Shell's Response

Shell says that it will provide the data.

RCB's Comments/Conclusions

Data gap 171-5: Reduction of Residue, is not yet fulfilled.

171-6: Proposed Tolerance

A tolerance proposal for the 24(c) use of monocrotophos on Bermuda grass grown for seed is required; if residues of monocrotophos concentrate in processed products from cottonseed, peanuts, or sugarcane, appropriate food/feed additive tolerances must be proposed.

Shell's Response

Shell does not intend to support the use on Bermuda grass.

Shell states that tolerances cannot be proposed until all residue work is completed; therefore an extension is requested.

RCB's Comments/Conclusions

The Bermuda grass Registrant should be notified that Shell does not intend to support the use of Azodrin on Bermuda grass, because this data gap needs to be resolved.

The due date for the processing studies on peanuts, sugarcane, and cottonseed is September, 1987. The due date for the tolerance proposals is also September, 1987.

RCB agrees that the tolerance proposals should await the completion of the requisite residue work. However the registrant will need to specify the extension needed before his request can be considered. Data gap 171-6 is not yet fulfilled.

171-7: Reasonable Grounds in Support of Petition

The rationale of how the residue data support the proposed tolerance is required to be submitted with any proposed tolerance.

Shell's Response

Shell requests an extension of this requirement until tolerances are proposed.

RCB's Comments/Conclusions

The due date for submitting grounds in support of any proposed tolerance is March, 1986. RCB will assume that the grounds in support of any proposed tolerances will be submitted with the relevant petitions. However, the registrant will need to specify the duration of the requested extension for his tolerance proposal (see RCB's Comments/Conclusions under 171-6) so that RCB can consider his proposal.

171-11: Tobacco

Data are not available to assess the exposure of man to residues of monocrotophos in or on green, freshly-harvested tobacco following multiple foliar applications of the 3.2 or 5 lb./gal SC/L at 1 lb. a.i./A; treatments should reflect the use of both ground and aerial equipment. Samples must be harvested 5 days after the last application. If residues are >0.1 ppm, additional data in which pyrolysis products are characterized must be submitted.

Also, the Office of the Assistant Administrator has requested TMP residue data on tobacco to determine whether detectable levels of TMP result from the use of monocrotophos on tobacco at the maximum registered rate.

Shell's Response

Azodrin is registered for use on tobacco at a rate of 1 lb. a.i./A. A 5 day PHI is in effect.

Shell has submitted the results of tobacco field trial conducted in GA. Tobacco received 2 applications with ground equipment at a rate of 1 lb. a.i./A. The treatment interval was 7 days, and PHI's of 0, 1, 2, and 5 days were observed. Leaf discs were collected with a leaf punch gun. The leaves were rinsed with an aqueous Triton solution prior to analysis. The Triton rinse and leaf discs were analyzed. The analytical methodology used to analyze residues of Azodrin and TMP was described under the Cottonseed section. The samples were stored frozen less than 2 months before analysis.

Recoveries of surface residues of TMP from the Triton rinse of tobacco leaves fortified at levels of 0.03-0.12 ppm ranged from 76-88%. Recoveries of non-dislodgable residues of TMP from the tobacco leaf discs fortified at levels of 0.03-0.07 ppm ranged from 78-104%.

The recovery of surface residues of Azodrin from the Triton rinse

of tobacco leaf discs fortified at levels of 0.06-71 ppm ranged from 71-132%. The recovery of nondislodgable residues of Azodrin from the tobacco leaf discs fortified at levels of 0.06-14 ppm ranged from 68-115%

Representative chromatograms of samples of check, fortified, and treated tobacco leaves were submitted and support the claimed limit of detection of 0.01 ppm.

Residue levels of TMP and Azodrin on tobacco leaves are tabulated below.

Sample	PHI (days)	Azodrin (ppm)	TMP (ppm)
Leaf discs after Triton rinse	0	18-24	0.08
	1	24-28	0.03-0.04
	2	14-17	0.01-0.02
	5	7	<0.01
Triton rinse of leaf discs	0	60-70	0.16-0.19
	1	29-30	0.04
	2	11-15	0.01-0.02
	5	3.4-4.2	<0.01

Shell states that it will provide the data needed to support this use.

RCB's Comments/Conclusions

Only 2 applications were made in the tobacco field trial although the number of applications permitted is unlimited. The Registration Standard specified that multiple applications by aerial and ground equipment were needed to support this use. The registrant needs to supply the Azodrin residue data requested in the Monocrotophos Registration Standard. The registrant has the alternative of limiting the number of applications permitted to tobacco and limiting application to ground equipment only in a revised label so that the submitted residue data would be in harmony with his label.

The data gap regarding the levels of Azodrin and TMP on tobacco leaves treated according to the proposed use is not yet fulfilled.

The submitted residue data clearly establish that residue levels of Azodrin are >0.1 ppm 5 days after treatment according to the registered use. In order to support the registered use, additional data in which pyrolysis products are characterized must be submitted. This data gap is not yet fulfilled.

Note to PM: The RCB chapter of the Monocrotophos Registration Standard was modified by the Office of the Assistant Administrator after the completion of the chapter by RCB. RCB only became aware of this change after the registrant had submitted the subject response to the 3(c)2(b) letter. RCB would appreciate notification by the PM on any changes made on our final documents in the future.

An updated Table A for monocrotophos is attached.

Attachment 1: Table A (updated, 11 pages)

cc: A. Barton, Monocrotophos Reg. Std. File-W. Boodee, PMSD/ISB, R.F., Reviewer-Deyrup, W. Miller-PM #16, Circu., Monocrotophos Subject File
RDI:JHOnley:5/19/86:RDSchmitt:5/20/86
TS-769:RCB:CM#2:RM810:X7484:CDeyrup:cd:5/19/86