



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

7-15-85

R.F.

JUL 15 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 464-523 (RCB #992).
Chlorpyrifos Registration Standard.
Dow's Response of April 18, 1985 to Residue
Chemistry Data Gaps. Accession No. 257864.

FROM: Nancy Dodd, Chemist *Nancy Dodd*
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TO: J. Ellenberger/E. Allen, PM Team 12
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and

Amy Rispin, SIS
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Dow Chemical Company submits a letter dated April 18, 1985, in response to RCB's memorandum dated March 25, 1985, on chlorpyrifos reregistration. This Dow letter of April 18, 1985 is the petitioner's second response to Residue Chemistry data gaps listed in the document "Guidance for the Reregistration of Pesticide Products Containing Chlorpyrifos as the Active Ingredient" (issued September 28, 1984). Along with the letter, the petitioner has enclosed revised labels for sweet potatoes, cowpeas/lentils, bean and pea hay, and soybean forage, hay, and straw. The petitioner has submitted a notice of intent to cancel registration of Lorsban 3G on bananas. The petitioner has also mentioned that residue data on alfalfa forage and hay have been submitted. That residue data on alfalfa forage and hay will be forwarded by RD to RCB for review when the additional planned studies on alfalfa are submitted.

Tolerances (see 40 CFR 180.342) for the insecticide chlorpyrifos [0,0-diethyl-O-(3,5,6-trichloro-2-pyridyl) phosphorothioate] are established for combined residues of chlorpyrifos and its metabolite 3,5,6-trichloro-2-pyridinol (TCP).

The residue chemistry data gaps which the petitioner addresses in this submission of April 18, 1983 are listed below in abbreviated form as summarized in the RCB memorandum of March 25, 1985 (R. Loranger). The footnote numbers from the Residue Chemistry section of the Generic Data Requirements Table are included. Dow's current responses, reflecting RCB's conclusions in the RCB memorandum of March 25, 1985, are listed also. RCB's present conclusions regarding the petitioner's present plans to address the data gaps are based on RCB's conclusions in the memorandum dated March 25, 1985.

The petitioner states that the studies which will be conducted to fill the data gaps addressed in this letter of April 18, 1985 will be submitted to EPA by March 1986, except for studies on strawberries, for which EPA has agreed to an extension to December 1986.

171-4 Nature of Residue (Metabolism)

DATA GAP:

"Plants (Footnote 3) - Studies must be submitted concerning the metabolism of ring-labeled [^{14}C]-chlorpyrifos and metabolites, especially TCP, by corn and a representative legume and root crop. Radioactive residues must be characterized by a method such as GC or HPLC and verified by MS."

Dow's Response

Dow will conduct corn and sugar beet metabolism studies.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that a legume metabolism study will not be required provided that corn and root crop metabolism studies are provided which identify most of the residue. RCB also concluded that the residues should be identified by GC or HPLC and confirmed by mass spectroscopy.

RCB awaits submission of the above metabolism studies on corn and sugar beets to resolve the above data gap.

2

DATA GAP:

"Animals (Footnote 4) - Metabolism studies must be submitted for ruminants (dermal study on cattle using dip treatment) and for poultry (3 days of oral dosing)."

Dow's Response

Dow will conduct dermal (pour-on) goat and poultry (3 oral doses) metabolism studies. (The petitioner has no interest in supporting the dipping vat use on ruminants.)

ECB's Conclusion

ECB has previously concluded (R. Loranger memorandum, March 25, 1985) that the above animal metabolism data gap will be resolved when adequate dermal (pour-on) cattle and poultry (3 oral doses) metabolism studies are submitted.

ECB notes that the registered use is for beef cattle, not goats. However, goats are an adequate substitute.

ECB awaits submission of the above metabolism studies on goats and poultry to resolve the above data gap.

171-4 Magnitude of the Residue (Residue Studies)

DATA GAP:

"Sweet potatoes (Footnote 7) - Additional data are required with a 90-day PHI or the registrant should revise the labels to include a 125-day PHI."

Dow's Response

Dow has submitted revised draft labels for Lorsban 4E and Lorsban 15G which show addition of a 125-day PHI restriction for sweet potatoes.

ECB's Conclusion

This data gap for sweet potatoes is resolved.

DATA GAPS:

"Turnip (roots) (Footnote 8) - Additional residue data are required from TX and GA for at-plant and transplanting applications.
Turnip greens (Footnote 9) - As with turnip roots, additional data are needed from TX and GA for the planting and transplanting (directed spray to plant bases) uses of chlorpyrifos."

Dow's Response

Dow plans no additional studies on turnips (roots and greens) since the data gaps have been filled.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gaps on turnip roots and greens have been resolved.

DATA GAP:

"Broccoli and Brussels sprouts (Footnote 12) - Additional residue data are required from California for soil applications at planting and at transplanting."

Dow's Response

Dow plans to conduct "residue studies involving at-plant application of LORSBAN 4E or LORSBAN 15G at the rate of 1.38 oz ai/1000 feet of row followed by a directed spray application of LORSBAN 4E at the rate of 1.38 oz ai/1000 feet of row at 30 days postplant (transplant use)" in California for broccoli and brussels sprouts.

RCB's Conclusion

RCB awaits submission of the above studies to resolve the above data gap on broccoli and Brussels sprouts.

DATA GAP:

"Cabbage (Footnote 13) - Additional data are required for planting and transplanting uses of chlorpyrifos in NY, FL, TX, CA, and WI."

Dow's Response

Dow plans to conduct residue studies involving "at-plant application of LORSBAN 4E or LORSBAN 15G at the rate of 1.38 oz ai/1000 feet of row followed by a directed spray application of LORSBAN 4E at the rate of 1.38 oz ai/1000 feet of row at 30 days postplant (transplant use)" in Florida and Texas for cabbage.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that additional residue data on cabbage are needed only for FL and TX. Therefore, RCB awaits submission of the residue studies finished in FL and TX to resolve the above data gap on cabbage.

DATA GAP:

"Cauliflower (Footnote 15) - Additional residue data reflecting the at-planting soil treatment (15G formulation) are required in CA and HI or NY and OR. Also, tests must be conducted in the same sites for the transplanting use of the 4EC formulation."

Dow's Response

Dow plans to conduct "residue studies involving at-plant application of LORSBAN 4E or LORSBAN 15G at the rate of 1.2 oz ai/1000 feet of row followed by a directed spray application of LORSBAN 4E at the rate of 1.2 oz ai/1000 feet of row at 30 days postplant (transplant use)" in California.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that additional residue data on cauliflower are needed only for CA. RCB notes that the maximum registered application rate for Lorsban 15G is 1.38 oz ai/1000 ft of row. Therefore, Lorsban 15G should be applied at the rate of 1.38 oz ai/1000 ft of row, not 1.2 oz ai/1000 ft of row. RCB awaits submission of the residue studies in CA (with the above application rate adjustment for Lorsban 15G) to resolve the above data gap on cauliflower.

DATA GAP:

"Cowpeas/lentils (Footnote 17) - Separate tolerances of 0.1 ppm should be established on these commodities since the seed and pod vegetable group is now obsolete."

Dow's Response

"Revised draft labels for LORSBAN 50-SL which show deletion of these crops in the Use and Dosage Recommendation section were submitted to the EPA under cover of a separate letter on March 14, 1985."

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap would be resolved when revised labels were submitted with uses on cowpeas and lentils deleted. This data gap concerning cowpeas/lentils is now resolved.

5

DATA GAP:

"Dry beans/peas (Footnote 17) - Separate tolerances of 0.1 ppm should be established on these commodities since the seed and pod vegetable group is now obsolete."

Dow's Response

"A tolerance petition requesting that residue tolerances be established for the legume vegetable crop group to include beans and peas will be submitted to the EPA under cover of a separate letter."

RCB's Conclusion

This submission is currently under review by RCB.

DATA GAP:

"Lima beans (Footnote 18) - The tolerance is not supported due to the absence of data for lima bean cannery waste. However, similar data requested for snap beans can be used to satisfy this requirement."

Dow's Response

Dow plans no additional studies on lima beans since the data gap has been filled.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap on lima beans has been resolved.

DATA GAP:

"Snap beans (Footnote 19) - The following data are required:
(A) Residue data from snap beans taken at maturity from plants raised from treated seeds in Oregon.
(B) Residue data for cannery waste from processing of snap beans having detectable weathered residues as a result of being grown from treated seed."

Dow's Response

Dow plans no additional studies on snap beans since the data gap has been filled.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap on snap beans has been resolved.

DATA GAP:

"Soybeans (Footnote 20) - Data are required for beans which have been harvested 28 and 40 days after the last of 6 foliar applications (aerial and ground) which were preceded by at-planting or early postemergence treatment with the 15G formulation at 1.3 lb ai/A."

Dow's Response

Dow plans no additional studies on soybeans since the data gap has been filled.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap on soybeans has been resolved.

DATA GAP:

"Bean and pea forage and hay (Footnotes 22 and 25) - Residue data are required from dried hay, harvested at its normal time of maturity, from plants grown from treated seed in NY, OR, CA, WI, MI, and ND."

Dow's Response

"Revised draft labels for LORSSAN 50-SL which show feeding restrictions for bean and pea hay were submitted to the EPA under cover of a separate letter on March 14, 1985."

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap would be resolved when revised labels containing the bean and hay feeding restrictions are provided. This data gap concerning bean and pea forage and hay is now resolved.

DATA GAP:

"Compea and lentils forage and hay (Footnote 23) - Tolerances must be prepared for these commodities or a crop group tolerance established for the Foliage of Legume Vegetables Group."

Dow's Response

"Revised draft labels for Lorshan 50-SL which show deletion of these crops in the Use and Dosage Recommendation section were submitted to the EPA under cover of a separate letter on March 14, 1985."

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap would be resolved when revised labels were submitted with uses on cowpeas and lentils deleted. This data gap concerning cowpeas and lentils forage and hay is now resolved.

DATA GAP:

"Soybean forage, hay, and straw (Footnote 26) - Residue data must be obtained for these commodities following foliar applications with the 4EC formulation and at-planting use of the 15G product."

Dow's Response

"Revised draft labels for LORSEBAN 4E which show feeding and grazing restrictions for soybean forage, hay, and straw are enclosed."

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap would be resolved when revised labels restricting the feeding/grazing of these plant parts are provided. This data gap concerning soybean forage, hay, and straw is now resolved.

DATA GAP:

"Peppers (Footnote 27) - Residue data are required involving use of the 4 lb/gal EC formulation on peppers at 0.85 lb ai/A from field tests conducted in Israel using a PHI of 5 days and as normally grown for export to the U.S."

Dow's Response

"As we are unable to provide the requested data for peppers grown in Israel, we suggest that the Agency contact the Israeli representative who petitioned for residue tolerances on peppers under PP01E2523."

RCB's Conclusion

PP01E2523 for chlorpyrifos on peppers was submitted by Carmielit Portnoy Industries, Ltd., P.O. Box 13, Tel-Aviv 61000, Israel. Counsel for Carmielit Portnoy Industries, Ltd. at the time of the petition (1981) was Hamel, Park, McCabe, and Saunders, 1776 F Street, NW., Washington, DC 20005 (Phone No. (202) 785-1234).

RCB suggests that RD contact the petitioner concerning the data gap on peppers.

8

DATA GAP:

"Cranberries (Footnote 32) - Studies must be conducted in OR and WA reflecting two aerial applications of the 4EC product (1.5 lb ai/A)."

Dow's Response

Dow plans no additional studies on cranberries since the data gap has been filled.

RCB's Response

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap on cranberries has been resolved.

DATA GAP:

"Strawberries (Footnote 33) - Residue data are required from CA (73% of U.S. production) for strawberries which have been treated foliarly when buds first appear and again 10 to 14 days later. Data are also needed from OR or WA and ID for strawberries from plants which received preplant soil treatment the previous year. In the same studies some plants should receive foliar treatments to show the effect of combination of uses on first-year fruit production."

Dow's Response

"Residue studies involving foliar applications of LORSBAN 4E at the rate of 1 lb ai/A when buds first appear and again at 10 to 14 days later will be conducted in CA, ID, and OR or WA. In addition, the studies in ID and OR or WA will include a preplant soil treatment the previous year of LORSBAN 4E applied at the rate of 2 lb ai/A."

RCB's Conclusion

RCB awaits submission of the above residue studies on strawberries to resolve the above data gap.

DATA GAP:

"Sorghum grain (Footnote 36) - The following data are required:
(A) Data in KS reflecting three foliar treatments at 3-day intervals, starting at 50 percent bloom; both aerial and ground data.
(B) Florida data for at-planting granular use followed by the three foliar uses noted in (A).

9
244 A

(C) Data from TX for successive treatments (i) seed use, (ii) at-planting granular and (iii) foliar as in (A)."

Dow's Response

Dow plans no additional studies on sorghum grain since the data gap has been filled.

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap on sorghum grain has been resolved.

DATA GAP:

"Sorghum forage and fodder (Footnote 38) - The same three sets of data requested for sorghum grain in KS, FL and TX are required for these crop parts. Forage should be cut and analyzed 14 days after the final foliar treatment. Some forage should be dried to fodder and some ensiled prior to analysis."

Dow's Response

"A residue study involving an at-plant application of LORSEBAN 15G at the rate of 12 oz/1000 feet of row on sorghum followed by three foliar, ground applications of LORSEBAN 4E at the rate of 1/2 pint/A (equivalent to 0.25 lb ai/A) at 3-day intervals beginning when 50 percent of the seed heads are in bloom will be conducted in the State of Kansas."

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap would be resolved if the petitioner conducted one trial using both at-planting and foliar applications (three foliar applications at 3-day intervals) in KS. (RCB concluded that aerial data are not needed. Also, additional data from FL and TX will not be required provided the existing tolerances are shown to be adequate.) RCB awaits submission of the above study to resolve the above data gap on sorghum forage and fodder. RCB notes that the at-plant treatment with LORSEBAN 15G should be conducted with a 30-inch row spacing.

DATA GAP

"Alfalfa forage and hay (Footnote 40) - Additional data are required as follows: (A) Combined residues of chlorpyrifos and TCP 14 days after the fourth aerial application of 0.5 lb ai/A and 21 days after the fourth aerial application of 1.0 lb ai/A. Data should also include the residues from maximum use within the individual cuttings. (B) A processing study to determine residues in meal processed from hay containing detectable weathered residues."

10

Dow's Response

"Alfalfa Forage and Hay - Residue studies involving broadcast, ground applications of LORSBAN 4E at the rate of 1 quart per acre (equivalent to 1 lb ai/A) to three consecutive cuttings of alfalfa will be conducted in at least two states. A 21-day PHI use pattern will be used for both forage and hay. Concerning the 0.5 lb ai/A and 14-day PHI use pattern, enclosed are two copies of a letter report from J. H. Wetters entitled "Residues of Chlorpyrifos and 3,5,6-Trichloro-2-Pyridinol on or in Alfalfa Green Forage and Hay." Results for samples of forage and hay taken from the fourth cutting of alfalfa (each cutting receiving a treatment of LORSBAN 4E at the rate of 1 pint/A at 7 days before harvest) showed combined residues of chlorpyrifos and its pyridinol metabolite of 1.3 to 4.6 ppm on green forage and 4.8 to 14.5 ppm on cured hay. These results are based on studies conducted in Davis, California; Atkinson, Illinois; and Saginaw County, Michigan. Even though these data do not exactly represent a 0.5 lb ai/A and 14-day PHI use pattern, we believe they are adequate for the Agency to conclude that the established tolerances (4 ppm on alfalfa green forage and 15 ppm for cured hay) will not be exceeded by this use pattern. Finally, concerning residues on alfalfa seeds, residue studies involving broadcast, ground treatment of a single cutting will be conducted with both use patterns, i.e. 0.5 lb ai/A and a 14-day PHI as well as 1 lb ai/A and a 21-day PHI."

RCB's Conclusion

RCB previously concluded (memorandum of R. Loranger, March 25, 1985) that "studies are required from at least two states reflecting three applications (ground or aerial as convenient) over three consecutive cuttings. Both the 0.5 lb/14-day PHI and 1.0 lb/21-day PHI use patterns must be examined for both forage and hay." Also, "data should be supplied for seeds harvested 14 and 21 days after treatment with 0.5 and 1.0 lb ai/A, respectively. The seed data may be from one application to one cutting (i.e. the registrant does not have to spray two or three cuttings before allowing the alfalfa to go to seed)."

RCB can make no conclusion regarding the above data gap on alfalfa forage and hay until the planned alfalfa studies are submitted. The submitted residue data on alfalfa forage and hay will be forwarded by RD to RCB for review after results from the planned studies on alfalfa are submitted to the Agency.

DATA GAP

"Bananas (Footnote 43) - Information for regulatory purposes (rep. labels, English translations, etc.) must be collected and submitted on chlorpyrifos usage on bananas in countries which export bananas to the U.S."

Dow's Response

"Because LORSBAN 5G (EPA Registration No. 464-475) is currently not being used for control of pests on bananas, we have requested cancellation of the product registration. Enclosed is a copy of an EPA letter dated March 13, 1985 which shows the Notice of "Intent to Cancel the Registration" of LORSBAN 5G. Thus, we believe that copies of labels for LORSBAN 5G are not required."

RCB's Conclusion

RCB previously concluded (memorandum of R. Loranger, March 25, 1985) that foreign labels which describe use of the 5G product for banded soil applications were needed. Registration of LORSBAN 5G on bananas is now cancelled (conversation with Ed Allen of RD on July 9, 1985). This data gap concerning bananas is now resolved.

DATA GAP:

"Cottonseed (Footnote 44) - Data must be supplied reflecting five applications (both aerial and ground) in CA."

Dow's Response

"Residue studies involving foliar, ground treatments with LORSBAN 4E applied five times to irrigated cotton at the rate of 1 quart per acre (equivalent to 1 lb ai/A) will be conducted in California."

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that data from CA reflecting ground application to irrigated cotton would resolve the above data gap. (RCB concluded that aerial data are not needed.)

RCB awaits submission of the above residue study on cottonseed to resolve the above data gap.

12

DATA GAP

"Figs (Footnote 45) - Data must be submitted for fresh figs 7 months following soil application of 2 lb ai/A. Data must also be provided for dried figs prepared from fresh figs treated at that rate."

Dow's Response

"Because the data gap has been filled, no additional studies will be conducted."

RCB's Conclusion

RCB has previously concluded (memorandum of R. Loranger, March 25, 1985) that the above data gap on figs has been resolved.

Note to Product Manager:

This submission does not address Product Chemistry data gaps for chlorpyrifos. This submission addresses those Residue Chemistry data gaps which were outlined in RCB's memo dated 3/25/85.

cc: Circu, RF, Chlorpyrifos SP, W. Boodee, N. Dodd, R. Loranger,
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13