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AUG 3 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil: Case No. 0097: Chemical No. 081901: Reconsideration of the Requirement for a Feed Additive Tolerance for Residues of Chlorothalonil in Potato Processing Waste: CBRS Nos. 15223 & 15648: DP Barcodes D212906 & D215634.

FROM: William O. Smith, Chemist
Chemistry Pilot Review Team
Chemistry Branch II-Reregistration Support (CBRS)
Health Effects Division (7509C)

William O. Smith

THROUGH: Edward Zager, Chief
Chemistry Branch II-Reregistration Support
Health Effects Division

[Signature]

TO: Andrew Ertman
Reregistration Branch
Special Review & Reregistration Division (7508W)

The purpose of this memorandum is to withdraw a previous CBRS recommendation for a feed additive tolerance for combined residues of chlorothalonil and its 4-hydroxy metabolite (SDS-3701) in processed potato waste.

Background

A tolerance for combined residues of chlorothalonil and its 4-hydroxy metabolite (SDS-3701) has been established for potatoes at 0.1 ppm. Chlorothalonil is considered to be a carcinogen while SDS-3701 is not.

The registrant has conducted studies to determine if residues concentrate in any of the processed commodities of potatoes. Residues do not concentrate in granules or chips but the Agency has concluded that residues do concentrate in peels and that a feed additive regulation is required for processed potato waste. Since chlorothalonil is a carcinogen the Delaney Clause of section 409 of FFDCA forbids such a regulation.



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The registrant has claimed that chlorothalonil does not concentrate in potato peels but that only the 4-hydroxy metabolite (SDS-3701) does. It is proposed that a feed additive regulation for potato waste be established for SDS-3701 and that the regulation not include chlorothalonil. Thus, the regulation would be in compliance with the Delaney clause.

Conclusions

1. Residues of chlorothalonil do not concentrate in any processed commodities from potatoes.
2. If residues of SDS-3701 are present on potatoes they will concentrate $>2x$ in the wet peel fraction from processing.
3. The combined residues of chlorothalonil and SDS-3701 will not exceed the existing section 408 tolerance of 0.1 ppm as a result of presently registered uses.

Recommendation

We recommend that the registrant be informed that we no longer require the proposal of a section 409 feed additive tolerance for combined residues of chlorothalonil and SDS-3701 on processed potato waste.

Discussion

The registrant submitted further information (Document # RC-95-RPB-006-001 and Document # RC-94-JRF-1701-T; no MRID #'s assigned) and met with the Agency on May 3, 1995 for discussions. In arriving at our current recommendation we have given consideration to these data and discussions as well as revisions in Agency policy concerning establishment of 409 tolerances.

To support the claim that chlorothalonil does not concentrate in potato peels the registrant has shown that a processing study (1985; MRID 40183404) reviewed in the 1988 Residue Chemistry Chapter of the Chlorothalonil Draft FRSTR was not performed according to accepted commercial practices. In this study the potatoes were not washed before processing resulting in soil contamination of the wet peel fraction. The registrant's argument, which is supported by information in Document # RC-95-RPB-006-001, is that apparent concentration of chlorothalonil in wet peel was due to residues in the accompanying soil.

Another processing study was conducted in 1992 (MRID 42800501; see W. Smith; 12/15/93; D192291 for review). Residues of SDS-3701 concentrated in wet ($>2x$) and dry ($>7x$) peel. No other concentration or reduction could be inferred since residues were nondetectable (see Table 1).

Table 1. Residues of chlorothalonil, its 4-hydroxy metabolite (SDS-3701), and HCB in potato processed commodities from a 1992 study.

Location Commodity	Application Rate (lb ai/A) ^a	Residues (ppm) ^b			Concentration/Reduction Factors		
		Chlorothalonil	SDS-3701	HCB	Chlorothalonil	SDS-3701	HCB
Madison, OH Whole potatoes	45.6	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.00025, <0.00025 (<0.00025)	--	--	--
Washed potatoes	45.6	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.00025, <0.00025 (<0.00025)	--	--	--
French fries	45.6	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.00025, <0.00025 (<0.00025)	--	--	--
Wet potato peel	45.6	<0.01, <0.01 (<0.01)	0.02, 0.02, 0.02, 0.02 (0.02)	<0.00025, <0.00025 (<0.00025)	--	>2	--
Dry filtered peel	45.6	<0.01, <0.01 (<0.01)	0.06, 0.08, 0.07, 0.07 (0.07)	<0.00025, <0.00025 (<0.00025)	--	>7	--
Potato chips	45.6	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.00025, <0.00025 (<0.00025)	--	--	--
Potato granules	45.6	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.00025, <0.00025 (<0.00025)	--	--	--

^a Total seasonal application rate.

^b Average residues are listed in parentheses.

In the meeting of May 3, the registrant discussed chromatograms from this processing study. Chlorothalonil peaks were apparent in samples from both the RAC and wet peel at levels too low to quantify; however, the relative peak heights indicated strongly that chlorothalonil per se was reduced in wet peel rather than concentrated.

Data were also discussed in this meeting from a processing study conducted on potatoes that had received a postharvest treatment with chlorothalonil (Document # RC-94-JRF-1701-T). Residues of chlorothalonil were clearly confined to the peel and, with the inclusion of a washing step, residues in the wet peel fraction were at a lower concentration than in the RAC.

The Agency recently responded to the National Food Processors Association petition on issues related to our concentration policy and interpretation of the term "ready to eat" (Federal Register; Vol 60; June 14, 1995; pp. 31300 to 31308). As part of this response the Agency has revised its concentration policy in determining the need for section 409 tolerances. Our previous policy, which was applied in the case of chlorothalonil on potatoes, was to rigidly adhere to a "concentration in fact" trigger for 409 tolerances. If residues in a processed food or feed were concentrated over those in the RAC then a tolerance was required. In our revisions to this policy we take into account other factors including variability of the analytical method and the degree of rounding involved in establishing the section 408 tolerance.

It has been established that currently registered uses of chlorothalonil on potato foliage will

result in nondetectable residues on the tubers. In the only acceptable potato processing study (Table 1), residues of SDS-3701 were found to concentrate in wet peel; however, the total residues were well below the established section 408 tolerance of 0.1 ppm. These tubers were harvested from plants that had received exaggerated application rates (ca 5x seasonal maximum rate) and the total residues on wet peel were still < 0.03 ppm. Thus, the established tolerance of 0.1 ppm on potatoes is sufficiently high to cover any residues which may reasonably be expected to occur on potato waste. There is no need for the establishment of a section 409 feed additive tolerance on processed potato waste.

cc: W. Smith, Chlorothalonil Reg. Std. File, SF, RF, M. Clock (HED/RCAB), J. Frane (PSPS), R. Loranger (CBTS), Circ.

7509C:CB-II:WOS:wos:Rm805A:CM2:305-5353:7/25/95

RDI: Pilot Team (7/25/95) RPerfetti (7/26/95) EZager (8/01/95).

Record of Telephone Conversation

From: David Miller *DM*
Subject: Thiodicarb. Conversation re: CBRS Review dated 5/1/95
To: Bart Suhre, Section Head *B. Suhre*
Call With: Jim Barron, Rhone-Poulenc.
Tel. No.: (919) 549-2318
FAX No. : (919) 549-2545
Dates: July 27, 1995, 3:30 pm
July 28, 1995, 9:00 am

Jim Barron was referred to me by Bonnie Adler (SRRD). He wanted to discuss some of the issues raised in my 5/1/95 review of the magnitude of the residue and processing studies in cottonseed and soybeans (CBRS Nos. 8761 and 13472). He mentioned that he had some specific concerns and questions and inquired as to whether I would like to review the memorandum first and return his call tomorrow. I answered in the affirmative and indicated that I would return his call the following morning.

After reviewing the 5/1/95 review, I called Mr. Barron at Rhone-Poulenc. The following is a summary of the pertinent points of our discussion:

COTTON

Mr. Barron indicated that he agreed with most of the recommendations for label changes for cotton (namely, establishment of a PHI, a maximum seasonal number of applications, and minimum retreatment intervals). He indicated, however, that there is also an early season ovicide use which was not explicitly tested in the field studies which were reported to CBRS; Rhone-Poulenc was concerned that CBRS might require additional field trials to permit this early season ovicide use. This early season ovicide use typically occurs 100-150 days prior to harvest and 4-6 weeks prior to thiodicarb's later season use as a larvicide; the use rate is specified as 0.125-0.25 lbs ai/A. I indicated to Mr. Barron that as long as any revised label directions (for combined early season ovicide and later-season larvicide use) did not exceed the maximum seasonal use rate of 5.4 lbs ai/A/season actually tested in the field trials then any shift of later-season use to earlier-season use would not require additional field trials. In other words, the later season (larvicide) uses would represent a worst-case scenario and any (substituted) early-season ovicide application would be less burdensome. CBRS concludes that the field trials which were performed adequately support both the early-season ovicide and later-season larvicide uses, provided the following label modifications are made:

- The maximum cumulative rate is established at 5.4 lbs ai/A/season
- The maximum use rate per application is established at 0.9 lbs ai/application
- Any series of repeated applications will not exceed a total of 0.9 lbs ai/A per seven day period
- The label restriction on grazing forage is removed

I agreed that all other use directions for cotton could remain as presently approved.

Mr. Barron also asked about the requirement that additional field trials be performed to generate cotton gin-byproducts. I had indicated in the review that although cotton forage data had been generated by Rhone-Poulenc, this data was for a 0-day (and not a 28 day) PHI; the data was thus not able to be translated from 0-day forage to 28-day cotton gin byproducts. I reiterated that it was still necessary for them to perform the cotton-gin byproduct residue studies, that CBRS might accept a lesser number of field trials than indicated in our new guidance document, and that they should prepare a cotton gin by-product study protocol for our approval.

SOYBEAN

Mr. Barron and I also discussed the field trials conducted with soybeans. Following this conversation, CBRS concluded that the field trials which were performed are adequate to satisfy GDLN requirements provided the following label modifications are made for soybean:

- The maximum cumulative rate is established at 3.0 lbs ai/A/season.
- The maximum use rate per application is established at 0.75 lbs ai/application.
- Any series of repeated applications will not exceed a total of 0.75 lbs ai per seven day period.

I agreed that all other use directions for cotton could remain as presently approved.

Mr. Andrew requested that some form of written communication be sent to him regarding this conversation. I indicated that I would write this up as a "Record of Telephone Conversation" and either mail it or fax it to him. I indicated that this would be done by Wednesday of next week.

Conclusion

Since the current approved label directions do not specify a maximum seasonal rate or a maximum number of applications per season, CBRS 5/1/95 review required that the use directions be changed to be consistent with those uses tested during the field trial. Mr. Barron called to discuss these required changes, and CBRS indicated that his proposals were satisfactory and would satisfy the requirements of the 5/1/95 CBRS review.

I indicated to Mr. Barron that I would write this conversation up as a "Record of Telephone Conversation" and have it faxed to him. It would be placed in our files and also be sent to Bonnie Adler (SRRD) and Dennis Edwards (RD) for their reference.

cc: RF, SF, List A File, B. Adler (SRRD), D. Edwards (RD) DJM.
RDI: FSuhre:8/1/95;RPerfetti:8/2/95;EZager:8/1/95.