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

DEC 22 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil: Case No. 0097: Chemical No. 081901: ISK Biotech Letter Concerning Potato Processing Studies: CBRS No. 14830: DP Barcode D210209.

FROM: William O. Smith, Chemist
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THROUGH: Paula A. Deschamp, Section Head
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TO: Niloufar Nazmi
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The purpose of this memorandum is to comment on certain statements made by the registrant in a letter of 3/3/94 to D. Barolo.

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 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 and the Agency agrees with the registrant that residues do not concentrate in granules or chips. There is disagreement regarding whether residues concentrate in potato peels. If residues do concentrate in peels then a feed additive regulation is required for processed potato waste. Since chlorothalonil is a carcinogen the Delaney Clause of FFDCA forbids such a regulation.

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.

To support the claim that chlorothalonil does not concentrate in potato peels the registrant claims that a processing study reviewed in the 1988 Residue Chemistry Chapter of the Chlorothalonil Draft FRSTR was rejected by the Agency and is invalid because potatoes were subjected to exaggerated rates of chlorothalonil at dates later in the season than is normal cultural practice. We do not agree with the registrant in this assessment. Many processing studies are conducted on raw agricultural commodities that have been subjected to off-label applications. This does not necessarily invalidate a processing study that determines relative residue levels of the RAC and its processed commodities. The specific study that the registrant refers to (1985; MRID 40183404) was deemed inadequate because it did not include analysis of dry peels. In the data that were submitted (Table 1), potatoes containing 0.01 ppm of chlorothalonil yielded wet peels containing 0.04 ppm chlorothalonil. In these same samples, SDS-3701 was present at 0.03 ppm in the whole potatoes and at 0.47 ppm in the wet peels. Our conclusion from these data is that if residues of chlorothalonil occur on potatoes then both chlorothalonil and SDS-3701 concentrate in the peel of potatoes.

Table 1. Residues of chlorothalonil, its 4-hydroxy metabolite (SDS-3701), and HCB in potato processed commodities from a study conducted in 1985.

Location Commodity	Application Rate (lb ai/A) [a]	Residues (ppm) [b]			Concentration/Reduction Factors		
		Chlorothalonil	SDS-3701	HCB	Chlorothalonil	SDS-3701	HCB
State College, PA Whole potatoes	7.8	<0.01, <0.01 (<0.01)	0.01, 0.01 (0.01)	<0.003, <0.003 (<0.003)	–	–	–
Washed peeled potatoes	7.8	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Potato peels	7.8	0.02	0.14	0.003	>2	14	>1
Sliced potatoes	7.8	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Potato chips	7.8	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Diced potatoes	7.8	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Cooked potatoes	7.8	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–

Location Commodity	Application Rate (lb ai/A) [a]	Residues (ppm) [b]			Concentration/Reduction Factors		
		Chlorothalonil	SDS-3701	HCB	Chlorothalonil	SDS-3701	HCB
Granular, dehydrated potatoes	7.8	<0.01, 0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Powdered, dehydrated potatoes	7.8	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
State College, PA Whole potatoes	8.9	<0.01, <0.01 (<0.01)	0.01, 0.01 (0.01)	<0.003 [c] (<0.003)	–	–	–
Washed peeled potatoes	8.9	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Potato peels	8.9	0.05	0.31	0.003	>5	31	>1
Sliced potatoes	8.9	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Potato chips	8.9	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Diced potatoes	8.9	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Cooked potatoes	8.9	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Granular, dehydrated potatoes	8.9	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Powdered, dehydrated potatoes	8.9	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
State College, PA Whole potatoes	12.0	0.01, <0.01 (<0.01)	0.02, 0.02 (0.02)	<0.003, <0.003 (<0.003)	–	–	–
Washed peeled potatoes	12.0	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<0.5	–
Potato peels	12.0	0.02	0.15	<0.003	>2	7.5	–
Sliced potatoes	12.0	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Potato chips	12.0	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	0.003, <0.003 (<0.003)	–	<1	–

(continued; footnotes follow)

Table 1 *(continued).*

Location Commodity	Application Rate (lb ai/A) [a]	Residues (ppm) [b]			Concentration/Reduction Factors		
		Chlorothalonil	SDS-3701	HCB	Chlorothalonil	SDS-3701	HCB
Diced potatoes	12.0	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Cooked potatoes	12.0	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Granular, dehydrated potatoes	12.0	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
Powdered, dehydrated potatoes	12.0	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	–	<1	–
State College, PA Whole potatoes	16.2	0.01, 0.01 (0.01)	0.03, 0.03 (0.03)	<0.003, <0.003 (<0.003)	–	–	–
Washed peeled potatoes	16.2	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	<1	<0.3	–
Potato peels	16.2	0.04	0.47	<0.003	4	16	–
Sliced potatoes	16.2	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	<1	<0.3	–
Potato chips	16.2	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	<1	<0.3	–
Diced potatoes	16.2	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	<1	<0.3	–
Cooked potatoes	16.2	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	<1	<0.3	–
Granular, dehydrated potatoes	16.2	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	<1	<0.3	–
Powdered, dehydrated potatoes	16.2	<0.01, <0.01 (<0.01)	<0.01, <0.01 (<0.01)	<0.003, <0.003 (<0.003)	<1	<0.3	–

[a] Total seasonal application rate.
[b] Average residues are listed in parentheses.
[c] Second sample lost in analytical processing.

The above study did not include dry peels so further data were required by the Agency. Another study was conducted in 1992 (MRID 42800501; see W. Smith; 12/15/93; D192291 for review). The results of the processing study are presented in Table 2. Residues of SDS-3701 concentrated in wet (>2x) and dry (>7x) peel. No other concentration or reduction could be inferred for chlorothalonil residues of concern since residues were nondetectable.

Table 2. 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.

CBRS CONCLUSIONS AND RECOMMENDATION

The study reviewed in the 1988 Draft FRSTR shows that both chlorothalonil and SDS-3701 concentrate in the wet peel; the more recent study demonstrates that residue on wet peel concentrate on drying. The concentration factors are consistent with the theoretical concentration factors for these commodities and are consistent with the expectation that any residues of chlorothalonil, which is a nonsystemic fungicide, would be surface residues.

CBRS agrees with the registrant that any residues of chlorothalonil or SDS-3701 that occur on potatoes from uses on current labels will actually be reduced in processed commodities that are used directly as human food. If residues of chlorothalonil occur on potatoes they will be confined to the peel (livestock feed) during processing. Furthermore, residues of chlorothalonil are degraded rapidly in animal systems. It has been concluded that chlorothalonil residues (carcinogen) will not transfer to meat or milk commodities and that SDS-3701 (non-carcinogen) will comprise the terminal residue in these commodities (see W. Smith; 10/14/94; D199685); therefore, there is no human dietary carcinogenic risk incurred from livestock consumption of processed waste from potatoes treated with chlorothalonil.

These considerations notwithstanding, it is CBRS policy that if residues are shown to concentrate in any processed commodity, then a food or feed additive regulation is required for that commodity.

Therefore, we recommend that the registrant be notified that we consider the data in MRIDs 40183404 and 42800501 to confirm that the residues of both chlorothalonil and SDS-3701 can concentrate on potato peels and that a feed additive regulation is needed for the combined residues of chlorothalonil and SDS-3701 on processed potato waste.

cc: W. Smith, Chlorothalonil Reg. Std. File, SF, RF, Circ., A. Ertman (7508W).

7509C:CB-II:WOS:wos:Rm805A:CM2:305-5353:12/19/94
RDI: PDeschamp(12/20/94) MMetzger(12/22/94).