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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader
January 15, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

MEMORANDUM

SUBJECT: Methidathion. Reregistration Case No. 0034, Chemical No. 100301. Addendum to Residue Chemistry Chapter of RED. Registrant's Request for Continued use on Timothy and Alfalfa in Kittitas County, WA. CBRS Nos. 17292 & 17291. DP Barcodes D225985 & D227105.

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

THROUGH: R. B. Perfetti, Ph.D., Acting Branch Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

TO: John Redden, Chemical Review Manager
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

The Residue Chemistry Chapter for the Methidathion RED was completed on 6/11/96. We recommended that tolerances for grass, grass hay, alfalfa and alfalfa hay be revoked as all uses on these crops were to be canceled. Contingent upon the revocation of the major animal feed tolerances and cancellation of uses, it was also recommended that tolerances be revoked on meat, milk, poultry and eggs.

Ciba-Geigy, the only registrant for this chemical, has requested that we not revoke the tolerances on grasses and alfalfa in connection with the revocation of tolerances on livestock commodities. They wish to maintain methidathion use on timothy and alfalfa in Kittitas County, WA. Methidathion is used on timothy hay and timothy-alfalfa mixes (primarily timothy) in this one county under a Special Local Need registration. This crop is the number one cash generator in Kittitas County with over 30,000 acres in production. Approximately 85% of the hay is exported to Japan and Taiwan and methidathion is needed for control of grass scale, thrips and mites. The Kittitas County Hay Growers and Suppliers Organization indicates that there are no other

registered or potential alternatives to control these pests. According to the hay growers in Kittitas County, most of the hay that is not exported is consumed by horses, not by dairy or beef cattle; therefore, the potential for dietary intake of methidathion via meat and milk consumption is negligible. [The information summarized in this paragraph was taken from letters written by T. R. Hoffman, Washington State University Cooperative Extension to Fay Wilhite, Ciba-Geigy (2/29/96), and to Barry O'Keefe, EPA/OPP (9/10/96)].

CONCLUSIONS AND RECOMMENDATIONS

CBRS' reassessment of tolerances for the methidathion RED should be modified as follows:

1. The tolerances on alfalfa and alfalfa hay should not be revoked but should be lowered to 5 ppm and changed to tolerances with regional registration.

2. The tolerances on grass and grass hay should be changed to tolerances with regional registration for timothy and timothy hay at 5 ppm.

3. There is no reasonable expectation of finite residues of methidathion occurring on meat, milk, poultry or egg commodities from this limited use pattern on timothy and alfalfa; therefore, we continue to recommend for revocation of tolerances on these commodities.

DISCUSSION

Residue data in support of Registrant's Request

The residue chemistry chapter of the methidathion FRSTR 5/27/88 asked for additional residue data to support alfalfa and grass tolerances of 12 ppm. Rather than generate the data, Ciba-Geigy, in a letter to the Agency dated 1/21/91, requested an amendment to the registration of Supracide 2E to delete from the label the use on "alfalfa (pure stands or stands containing clover or grass) and pure stands of timothy grass". These uses were removed from labels.

The Washington Department of Agriculture issued a Special Local Need [24(c)] Registration to Ciba-Geigy Corp. on March 28, 1994 to allow application of Supracide 2E® (EPA Reg.# 100-501) and Supracide 25WP® (EPA Reg.# 100-754) to control grass scale, thrips, and spider mites in stands of timothy grass or mixtures of timothy-alfalfa.

This 24(c) registration was reviewed by J. Garbus of CBTS (5/9/94). In that review, CBTS pointed out deficiencies in the data. In a subsequent submission, the State of Washington provided additional details that were requested in the memo of J. Garbus concerning the residue data. This submission was reviewed by G. Herndon of CBTS (7/28/96). The timothy residue

data in the submission were deemed adequate to support the 24(c) registration if 24(c) labels were revised to impose a 21-day PHI and to limit the total amount of active ingredient per acre applied to the timothy or timothy/alfalfa stands per cutting to 1 pound. The recommendation was made for a new tolerance with regional registration for timothy grass and hay at 5 ppm. In addition, it was recommended that the registrant should perform residue trials on alfalfa using a 1 lb ai./A rate and a 21 day PHI and propose appropriate tolerances with regional registration to replace the existing 12 ppm tolerances on alfalfa and alfalfa hay.

We continue to recommend for the timothy tolerances of 5 ppm and also for tolerances of the same level on alfalfa and alfalfa hay. We are making this recommendation in the absence of further field trials on alfalfa for the following reasons:

> A total of 59 residue trials carried out in 11 states were submitted and reviewed in conjunction with PP#7F1983 (see memo of R. Perfetti dated 5/24/78). Residue levels in alfalfa ranged from 0.13 to 25 ppm 6 to 12 days after making 1 to 12 applications of 0.5 to 1.0 lb.ai./A. Based on the data submitted, RCB recommended that a 12 ppm tolerance and 14 day PHI be proposed. Field trial data demonstrate that residues of methidathion decline rapidly with time. Although data are not available for the 21-day PHI on alfalfa, the rapid decline evident in the above residue trials as well as a rapid decline noted in the timothy data allow an extrapolation/ translation of data to support this tolerance. CBRS concludes that residues on alfalfa will not exceed 5 ppm with a 21-day PHI.

<u>Transfer of residues to meat, milk, poultry and eggs</u>

The HED Metabolism Committee (4/4/95) considered the cholinesterase inhibiting potential of methidathion and its identified metabolites as well as the levels of each compound observed in the plant and livestock metabolism studies. Residues of parent are higher than any metabolite in citrus, alfalfa and beans. Also, no residues of methidathion sulfide, sulfoxide or sulfone were observed in plant matrices. Low levels of methidathion (<5-32 pp**b**) were observed only in fat matrices in livestock at dose rates of 10 to 110 times the maximum theoretical dietary burden for poultry and ruminants.

The Metabolism Committee concluded that;

1) The cholinesterase inhibitors observed in the metabolism studies were parent, oxon and the desmethyl metabolite.

2) The oxon is present at levels considerably less than the parent and since it is a rat metabolite its toxicity would have been accounted for in the TOX studies. The desmethyl metabolite would likely be a significantly less potent cholinesterase inhibitor compared to the parent or oxon. Therefore, risk assessment using parent only will adequately account for risks resulting from all cholinesterase inhibiting metabolites and only the parent compound need be included in the

tolerance expression.

3) The sulfide, sulfoxide and sulfone metabolites are not considered to be cholinesterase inhibitors.

Based on these considerations, the Committee decided that the residue to be regulated in plants and livestock is parent compound only and that, since no real levels of cholinesterase inhibitors were expected in livestock commodities under the theoretical maximum dietary burden, this was considered to be a 40 CFR 180.6(a)(3) situation with respect to livestock commodities and therefore the tolerances in/on these commodities should be revoked. This conclusion regarding the need for tolerances on livestock commodities required that the registrations/tolerances on alfalfa, clover and grasses be canceled/revoked. It was noted that any additional uses resulting in residues of methidathion in/on livestock feed items may engender the need for tolerances in/on meat, milk, poultry and eggs.

The present SLN use potentially could be a source of transfer to residues to cattle via the forage or hay. According to Table 1 of the Test Guidelines for Residue Chemistry (OPPTS No.860.1000) the maximum potential for transfer of residues would be in a dairy cow's diet. Alfalfa hay or forage could conceivable make up as much as 70% of a cow's diet. The following table, taken from the metabolism committee briefing memo (R.B.Perfetti, 3/27/95), demonstrates that with tolerance levels of 5 ppm on alfalfa and timothy commodities there is no expectation of detecting residues of methidathion in meat, milk, poultry and eggs. Therefore, we continue to recommend for revocation of these tolerances.

TABLE 1: Residues Of Methidathion Observed in Livestock Metabolism Studies.
[% TRR For Each Metabolite; Numbers In Parentheses Are PPM]

SPECIES	DOSE LEVEL	SAMPLE	TRR (ppm)	PARENT	OXON	DES-METHYL	SULFIDE	SULFOXIDE	SULFONE	RH METABOLITE
Hen	40 ppm (98X)	Liver	2.55	-	-	-	-	0.12 (0.003)	10.2 (0.26)	4.4 (0.11)
		Muscle	0.28	-	-	-	-	2.32 (0.01)	49.6 (0.14)	13.6 (0.04)
		Fat	0.15	20.1 (0.032)	-	-	-	2.5 (0.004)	36.8 (0.06)	20.5 (0.03)
		Egg	0.29	-	-	-	-	14.2 (0.04)	47.8 (0.04)	12.1 (0.04)
Hen	45.3 ppm (110X)	Liver	3.85	-	-	12.3	-	-	-	-
		Muscle	0.32	-	0.8 (0.003)	0.4	-	-	1.5	6.7 (0.02)
		Fat	0.23	-	-	-	-	-	-	-
		Egg White	1.01	-	-	2.8	-	5.4 (0.13)	14.9(0.05)	2.6 (0.03)
		Egg Yolk	0.43	-	-	1.2	-	8.2 (0.4)	18.3 (0.04)	1.6 (0.01)
Goat	47.5 ppm (10.4X)	Liver	1.67	-	-	2.9 (0.05)	6.2 (0.1)	0.3 (0.005)	2.6 (0.04)	12.1 (0.2)
		Kidney	1.05	-	-	8.3 (0.09)	4.8 (0.05)	0.4 (0.004)	3.7 (0.04)	20.6 (0.22)
		Muscle	0.29	-	-	-	-	15.3 (0.04)	32.5 (0.09)	29.5 (0.08)
		Fat	0.14	<3.8 (<0.005)	-	-	3.8 (0.005)	3.9 (0.03)	6.6 (0.01)	71 (0.1)
		Milk	0.8	-	-	2.8 (0.02)	-	-	2.5 (0.02)	4.5 (0.04)
Cow	39 ppm (8.6X)	Milk	0.8	-	-	-	-	8 (0.06)	4 (0.03)	-
Cow	1 mg/kg	Milk	ND	-	-	-	-	-	-	-

The registrant should be advised that the conclusions in this memorandum apply only to this special local need use. If any further uses of methidathion are sought on these crops then further data may be required. Also, any additional uses resulting in residues of methidathion in/on livestock feed items may engender the need for tolerances in/on meat, milk, poultry and eggs.

Science Analysis Branch has requested an anticipated residue estimate for use in an acute dietary exposure assessment for the Methidathion RED. It should be noted that the conclusions in this memorandum do not have an impact on that estimate as there are no changes in our recommendations for tolerances on food items.

cc: Reviewer(W. Smith), Reg. Std. File, B. O'Keefe (SRRD), RF, SF, Circ.

RDI:Pilot Team:11/20/96:RPerfetti:11/21/96
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