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MEMORANDUM

SUBJECT: Review of Additional Information on the Fish Accumulation Study (MRID 41444206) and Clarification on the Status of Confined Rotational Crop and Field Volatility Data Requirements for Amitraz

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THRU: Mr. Henry Jacoby, Branch Chief
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TO: Mr. Dennis Edwards, Team Reviewer
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Registration Division (H7505C)

General: EFGWB requested additional information on the TLC separation efficiency of parent amitraz and its degradates 2,4-dimethylformanilide (BTS 27919), N-2,4-dimethylphenyl-N-methylformamidine (BTS 27271), and 2,4-dimethylaniline (BTS 24868) in the fish accumulation study (MRID 41444206). The registrant, NOR-AM, responded to EFGWB's request by explaining that the TLC separation efficiency in three different solvent systems was adequate to quantify amitraz and its degradates in fish tissue extracts. However, EFGWB requested additional quantitative or qualitative information on TLC separation efficiencies of amitraz and its degradates.

This memorandum provides further clarification on the TLC separation efficiency of parent amitraz and its degradates (e.g. BTS 27919, BTS 27271, and BTS 24868) in fish tissue extracts from the fish accumulation study (MRID 41444206).

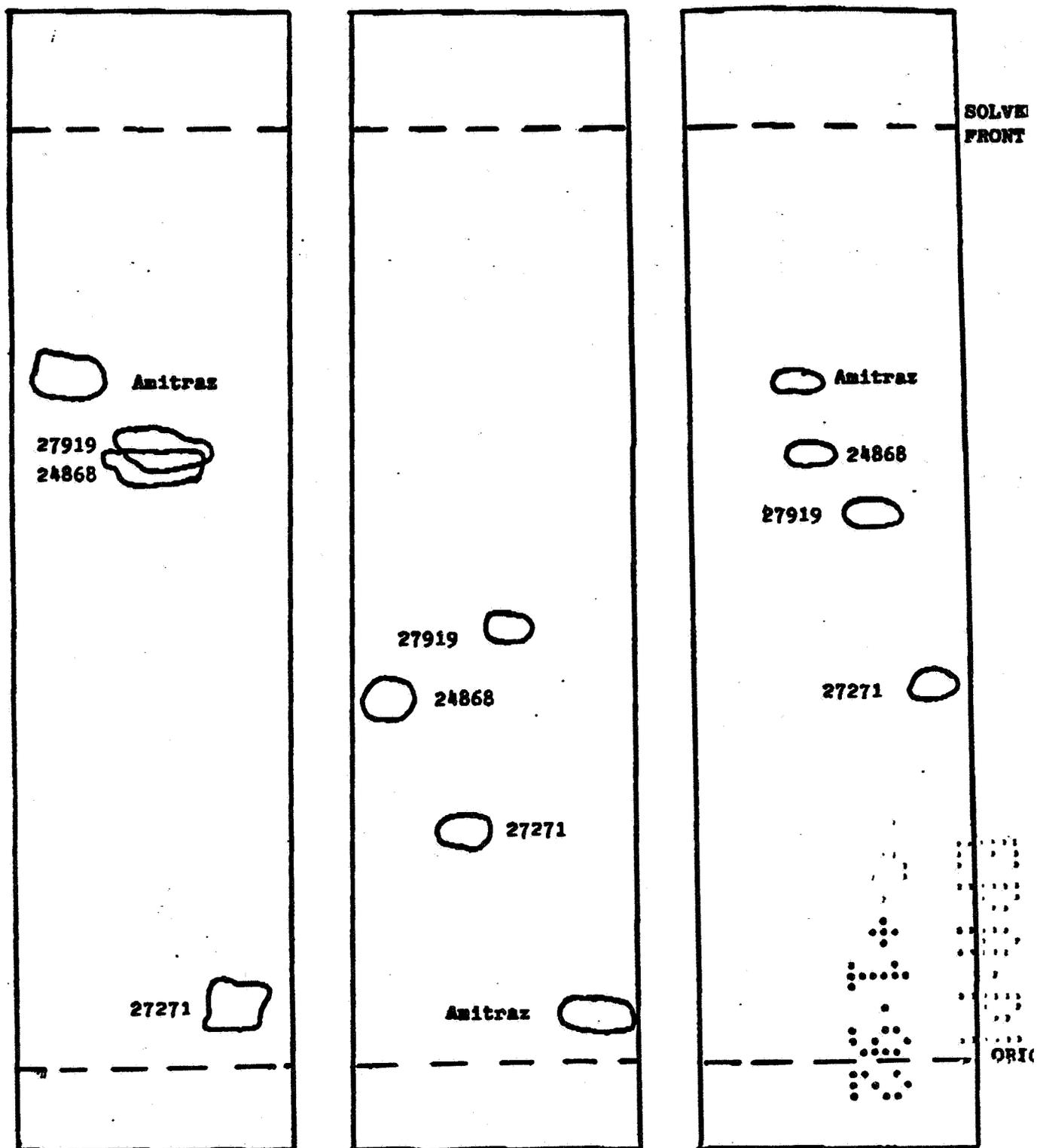
NOR-AM submitted TLC separation diagrams of reference standards of parent amitraz and its degradates in fish tissue extracts. See attached Figure 1. EFGWB believes the diagrams indicate that amitraz and its degradates can be adequately separated using methanol:water:ammonia and chloroform:ethyl acetate:ammonia solvent systems; however, the chloroform:ethyl acetate solvent does not provide adequate separation of BTS 27919 and BTS 24868. The separation of ¹⁴C-amitraz residues is shown in Table 1. This additional information is adequate to supplant any previous comments regarding the TLC separation efficiency of amitraz and its degradates in fish tissue extracts. Therefore, the fish accumulation study (MRID 41444206) provides acceptable data to fulfill the 165-4 data requirement.

There are no acceptable confined rotational crop data for amitraz at this time. However, previously submitted and acceptable field rotational crop studies partially describe the potential accumulation in rotated crops. EFGWB suggests that confined rotational crop data be required as a condition of registration to use amitraz on cotton.

As previously addressed in a memorandum (dated November 4, 1992) from EFGWB to SRRD, BTS 24868 and CO₂ were identified as the only volatile degradates in an acceptable laboratory volatility study (MRID# 40780518). Because the amitraz degradate BTS 24868 appears to be of minimal human and ecological toxicological concern, EFGWB believes the data requirement should be reserved at this time. EFGWB notes BTS 27271 and BTS 27919 have reported vapor pressures of 0.12 Pa and 4.1×10^{-4} Pa, respectively (MRID# 422063-01, 422063-03, 422063-02).

cc: Mario Fiol, SRRD (H7508W) ✓
Meredith Johnson, RD (H7505C)

FIGURE 1 : Relative Separation of the Reference Compounds in the Solvent Systems Used



1. Chloroform : ethyl acetate
2. Methanol : water : ammonia

3. Chloroform : ethyl acetate : ammonia

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TABLE 1 DISTRIBUTION OF ¹⁴C PRODUCTS ON TLC PLATES AS PERCENTAGE OF THAT IN TISSUE EXTRACTS

Tissue Type	TLC SOLVENT SYSTEM/IDENTIFIED COMPOUNDS														
	CHLOROFORM:ETHYL ACETATE			METHANOL:WATER:AMMONIA			CHLOROFORM:ETHYL ACETATE:AMMONIA			METHANOL:WATER:AMMONIA					
Extract	Amitez	BTS 27271	BTS 27919/24868 Combined	Amitez	BTS 27271	BTS 27919	BTS 24868	Amitez	BTS 27271	BTS 27919	BTS 24868	Amitez	BTS 27271	BTS 27919	BTS 24868
Viscera	Ethyl Acetate	2.36	0.88	1.10	1.44	0.84	0.29	0.33	2.68	0.61	0.37	0.26			
	Methanol	0.04	0.61	0.56	ND	ND	0.18	0.58	0.16	ND	0.14	0.25			
Flesh	Ethyl Acetate	1.86	3.31	1.66	1.51	1.36	0.59	0.88	1.75	1.11	1.22	0.44			
	DCM	0.42	0.49	2.32	0.14	0.39	1.67	1.21	0.12	0.45	1.61	0.25			
Carcass	Methanol	0.11	0.39	3.20	0.14	0.03	0.82	3.14	0.44	ND	1.53	1.75			
	Ethyl Acetate	6.87	11.22	3.72	3.12	8.82	1.95	2.55	6.66	6.66	2.79	1.17			
Methanol	DCM	1.08	13.52	16.25	0.29	12.48	5.35	12.32	4.02	12.38	6.59	3.55			
	Ethyl Acetate	0.16	0.54	4.97	0.25	ND	1.16	4.67	1.06	ND	2.09	1.76			

ND - not detected.

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