(F) 3148 Kathy Davis

P-542 126 309

DOW CORNING

[redacted]

October 31, 1989

Document Processing Desk (Phase 2 Response)
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Reference: DOW CORNING CORPORATION PHASE 2 REREGISTRATION RESPONSE TRIMETHOXYSILYL QUATS CASE No.3148, CHEMICAL NUMBER 107401

Dear Sir:

The report references (MRID) of studies filed with EPA in support of registration guideline requirements are incomplete. The Pesticide Document Management System Guideline Sequence Bibliography, Report ID: PDR20B04 does not include all relevant studies or information filed by Dow Corning Corporation in support of registrations 34292-1, 34292-2 and 34292-3.

The absent information includes chemistry, toxicology, and use instruction submissions too numerous for practical listing or resubmission. EPA accession numbers have been provided where available for studies not included on the PDMS report.

It should also be noted that MRID 00164909 is incorrectly identified as a submission of Dow Chemical U.S.A. (1977). An inspection of this report at EPA confirmed it to be a Dow Corning Corporation submission.

Accordingly, the attached reregistration response is a good faith effort to comply within the limitations of available information.

At such time as a complete PDMS Guideline Sequence Bibliography Report can be made available, we will update the response to incorporate all references.

As directed in the Response Worksheet instructions, Attachments I and II have been included to explain why an identified requirement does not apply.

Respectfully Submitted,

Arthur A. Birdsall

Arthur A. Birdsall
Manager, Product Stewardship, Safety and Compliance

CERTIFIED MAIL; RETURN RECEIPT

Attachment II

DOW CORNING CORP. Reregistration Phase 2 Response

Reregistration Request Letter

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

August 23, 1988

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

RECEIVED

AUG 2 [illegible]

HEALTH & ENVIRONMENTAL SCIENCES

Dow Corning Corporation
2200 W. Salzburg Road
Midland, MI. 48686-0994
Attn: E. Anthony Abbott

Dear Mr. Abbott:

Subject: Letter dated August 26, 1987
EPA Reg. No. 34292-1

This responds to your subject letter which included data to partially complete the requirements of the antimicrobial data call-in issued March 4, 1987 and a proposed justification for not submitting additional toxicological data.

A list of the studies submitted and their core classification appears below.

1.	Acute Toxicity*	
	a. Acute Oral LD_{50}	Core: Minimum
	b. Acute Dermal LD_{50}	Core: Minimun
	c. Primary Eye Irritation	Core: Minimum
	d. Primary Skin Irritation	Core: Supplementary
2.	Human Repeated Insult Patch Test*	Core: Invalid (IBT)
3.	28-Day Subacute Dermal Toxicity With Treated Fabric in Albino Rabbits	Core: Invalid (IBT)
4.	Acute Vapor Inhalation* Toxicity	Core: Invalid (IBT)
5.	Host-Mediated Assay for Detection of Mutagens*	Core: Invalid (IBT)

6.	Vaginal Irritation Study in Dogs	Core: Invalid (IBT)
7.	32-Day Human Exposure to Treated Socks	Core: Supplementary information
8.	3-Month Human Wear Test of Treated Athletic Socks	Core: Supplementary
9.	Teratology Study in Rats*	Core: Invalid (IBT)
10.	Mutagenicity Evaluation of Q9-DC5700*	Core: Unacceptable
11.	Mammalian Cell Transformation Without Exogenous Activation*	Core: Unacceptale
12.	Mammalian Cell Transformation With Exogenous Activation*	Core: Unacceptable
13.	Durability (Leaching Study)**	Core: Minimum
14.	Percutaneous Absorption in Rabbits**	Core: Supplementary
15.	Determination of Respirable Particle Size	Core: Supplementary study
16.	Acute Aerosol Inhalation*	Core: Invalid (IBT)

Under the option selected in the antimicrobial data call-in, the following studies are required:

90-day Dermal

Teratology

Mutagenicity battery

Exposure information

(*) Study relevant to evaluation of product
(**) Special study required by Toxicology Branch

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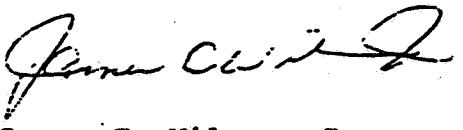
EPA evaluated your exemption requests. In the absence of other factors (closed delivery system, information in the public literature, active ingredient determined to be innocuous, etc.) which would allow EPA to evaluate properly the potential hazards associated with the use of antimicrobial pesticides, a minimum set of data is required on each active ingredient. Based on our assessment of the environmental characteristics, physicochemical properties, and qualitative estimations of exposure for these chemicals, these data represent the absolute minimum that is necessary to make the statutory risk and benefit determinations.

You are reminded that the technical manufacturer of the active ingredient chemical is responsible for development of toxicology data. Toxicology testing is conducted on active ingredients, not on end-use products. However, if the technical manufacturer does not commit to develop the data, then the end-use producers are responsible for the generation of the data to maintain their product registrations.

We recommend that you consider sharing in the cost of the development of the data with other registrants of products containing the active ingredient in question. This method is discussed on pages 11-12 of the Notice.

Sincerely,



703-557-3675

James E. Wilson, Jr.
Antimicrobial Program Branch