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

24 SEP 1986

CERTIFIED MAIL

NOTE: Some information in this letter may be entitled to treatment as trade secret or proprietary data under FIFRA.

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Rohm & Haas Company
Independence Mall West
Philadelphia, PA 19105

Subject: Cancellation of Pesticide Products Containing Dicofol for Failure to Comply with the May 29, 1986, Notice of Intent to Cancel

Dear Registrant:

On May 29, 1986, the Agency published in the Federal Register (51 FR 19508-19525) a Notice of Intent to Cancel Registrations of Pesticide Products Containing Dicofol ("Dicofol Cancellation Notice"). This letter notifies you that since you have failed to comply with the terms of the Dicofol Cancellation Notice, the registrations of your products listed in Attachement A have been cancelled by operation of law. The effective date of cancellation was June 29, 1986.

The Dicofol Cancellation Notice found that pesticide products containing dicofol were contaminated with a group of chemical compounds, including DDT, DDE, and other structurally similar compounds, which caused significant adverse effects on the environment by harming both fish and avian species, including endangered species. The Agency also concluded that the risks caused by these contaminants (referred to as "DDTr"), together with other risks of dicofol, outweighed the benefits of using dicofol and that the registrations of dicofol products should be cancelled.

The Dicofol Cancellation Notice further determined, however, that dicofol products could meet the statutory standards for registration if certain modifications of the terms and conditions of registration were made by registrants. Specifically, in order to continue your registrations, you were required by the Notice to submit for each product containing dicofol: an application for amended registration; revised product labeling; and a new confidential statement of formula which certified an upper limit for DDTr equal to or less than 2.5 percent of the amount of technical grade dicofol in the product. Information showing that you could produce your product with no more DDTr than the amount certified as the upper limit was also required to accompany the formula statement.

These submissions were required to be filed with the Agency within 30 days after you received a copy of the Dicofol Cancellation Notice or publication of the Notice in the Federal Register, whichever was later. According to EPA records, counsel for Rohm & Haas received a copy of the Dicofol Cancellation Notice on May 22, 1986, the day on which the Notice was signed. In EPA's view, this constituted receipt by Rohm & Haas of the Dicofol Cancellation Notice. Thus, the deadline for receipt by EPA of the required application, confidential statement of formula, supporting product chemistry data, and revised labeling was June 29, 30 days after publication of the Notice in the Federal Register.

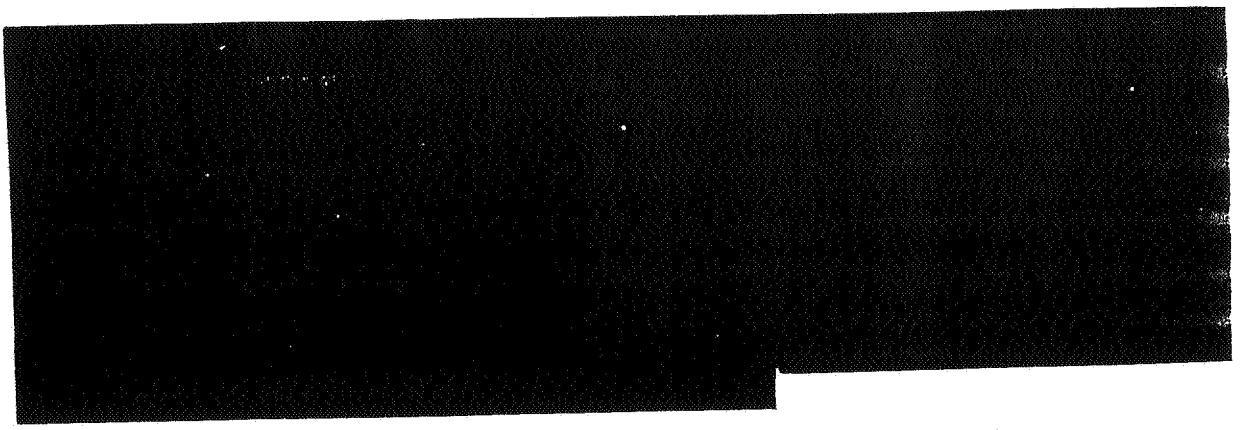
The Agency received on July 21, 1986 applications for amended registration, revised labeling, and revised confidential statements of formula for your products containing dicofol, as well as limited product chemistry information pertaining to the technical grade dicofol product as currently manufactured by Rohm & Haas Company. Additional product chemistry information was submitted on August 29, 1986.

Your failure either to request a hearing or to submit the required materials in a timely fashion means that you failed to comply with the requirements of the Dicofol Cancellation Notice, and your registrations, therefore, have been cancelled by operation of law, effective June 29, 1986. See FIFRA § 6(b) and Dicofol Cancellation Notice, 51 FR 19,525.

EPA has reviewed your untimely submissions and, as explained below, has further determined that they also fail to comply with the substantive requirements of the Dicofol Cancellation Notice. This provides an additional, independent basis for the cancellation of your dicofol products.

The Agency has completed review and evaluation of your formula statements and product chemistry data and has concluded that these data demonstrate that your dicofol products contain DDTr contaminants at a level greater than 2.5% of the amount of technical grade dicofol in the products.

The confidential statement of formula dated July 9, 1986, submitted on July 21, 1986, for Kelthane® Technical (EPA Registration No. 707-107), certifies an upper limit of 2.5% for [redacted] as DDTr impurities. [redacted] the o,p'- and p,p'- isomers of DDT, DDE, DDD, and extra-chlorine DDT (Cl-DDT). [redacted]



In your letters of July 17, and August 29, 1986, you claimed that DDTr consists only of the eight specific components [redacted] This position apparently is based on the language in the Dicofol Cancellation Notice which states that:

> All dicofol products contain as impurities a group of chemically similar compounds including the o, p' and p, p' isomers of DDT, DDE, DDD, and of a chemical referred to as extra-chlorine DDT (CI-DDT). . . . These DDT-related substances are collectively referred to as DDTr.

51 FR 19,510-11.

Your interpretation of the term, "DDTr", is fundamentally inconsistent with both the literal language of the Dicofol Cancellation Notice and the intent of the Notice to establish a limit on the amount of DDT and closely related compounds added to the environment as the result of dicofol use.

The Dicofol Cancellation Notice contains several passages explaining that the term DDTr applies to a broad group of contaminants. On page 19,508 EPA explained that it had initiated its Special Review of dicofol "because EPA believed that there were substantial risks to the environment associated with the presence of DDT and related impurities (DDTr) as contaminants of technical dicofol." (Emphasis added). Later, EPA elaborated that the Special Review "was based on the concern that dicofol is contaminated with DDT, DDE, and/or closely related compounds (collectively referred to as DDTr) that can cause significant adverse effects on nontarget wildlife." 51 FR 19,508 (emphasis added.) In describing the scope of the Agency's concern about risks to nontarget wildlife, EPA again explained that DDTr was "a group of chemically similar

compounds" which were "DDT-related substances" and gave a list of eight compounds specifically included within the term. */ See 51 FR 19,510-11 quoted above. Finally, EPA explained in its discussion of the risk to nontarget species that all of the constituents of DDTr were regarded as having toxic properties similar to DDT and DDE, because of the close resemblance of their chemical structures to DDT and DDE. 51 FR 19,512.

Taken together, these passages reflect a consistent position that DDTr refers to the chemical contaminants of dicofol which are structurally related or similar to DDT. [redacted]

In addition to your interpretation of the term DDTr, your August 29, 1986 letter implies that EPA has never before expressed concern about contaminants other than the eight specific compounds listed in the Dicofol Cancellation Notice (the o,p' and p,p' isomers of DDT, DDE, DDD, and Cl-DDT). This implication is simply incorrect. The Agency's Registration Standard on dicofol issued in 1983 made clear the Agency's need for accurate product composition information. Every subsequent review of Rohm and Haas' product chemistry submissions has pointed out the need to characterize product composition fully. The Agency has repeatedly requested that Rohm & Haas identify the previously unidentified peaks in the chromatogram of the Kelthane Technical. Agency reviews of product chemistry, transmitted to Rohm & Haas with our letters of April 22, and May 24, 1985, expressed the need for identification of the unknown impurities. Even as early as November 16, 1984, we informed you that [redacted] unidentified ingredients (as listed on your confidential statement of formula at that time) must be identified. Thus, EPA's frequently repeated concern with the uncharacterized contaminants of dicolfol technical is entirely consistent with the Agency's definition of DDTr.

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*/ The conclusion that the eight compounds listed in the Dicofol Cancellation Notice were merely examples of DDTr and not a comprehensive list is supported by the fact that numerous other isomers and chlorinated analogs of DDT, DDE, DDD, and Cl-DDT also exist. EPA included only the o,p'- and p,p'- isomers as examples because they historically have been the most commonly identified DDTr contaminants in dicofol.

In sum, the term, DDTr, applies to all compounds which are structurally related to DDT and which are present as contaminants of your technical grade dicofol products, whether or not they were specifically listed in the Dicofol Cancellation Notice. Because the upper certified limits for DDTr compounds in your technical dicofol product total between [redacted] percent of the product, your submission in response to the Dicofol Cancellation Notice does not satisfy the substantive requirements of the Notice. Accordingly, the registration of your technical grade dicofol product (EPA Reg. No. 707-107) has been cancelled by operation of law, effective June 29, 1986. [redacted] your end-use formulations, these registrations are also not in compliance with the terms of that Notice, and therefore have been cancelled. The effective date of these cancellations is also June 29, 1986. */

For reasons detailed above, the Agency requests you to remove from the market the following pesticide products containing dicofol:

1. all dicofol products which have been produced on or after June 29, 1986, and

2. all dicofol products which were considered to be existing stocks on May 29, 1986, which were released for sale or distribution after June 30, 1986, and which did not bear the labeling required by the May 29, 1986 Federal Register Notice. (See Dicofol Cancellation Notice Unit IV. D. 2., 51 FR 19519.)

Specifically, the Agency requests that:

1. your company initiate procedures to determine the locations of all quantities of these products and the amounts of each product at each location,

2. your company take whatever steps necessary to insure that these products are returned to your company from all such locations, and

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*/ It should be noted that this letter of cancellation is consistent with a biological opinion issued by the Interior Department's Office of Endangered Species ("OES") in March, 1986. In that biological opinion, OES informed EPA that the use of dicofol containing in excess of 0.1% DDTr is likely to jeopardize the continued existence of the Pacific States population of the American peregrine falcon. Accordingly, EPA required a phase-out of dicofol with greater than 0.1% DDTr in the technical grade of the product.

3. you inform the EPA Regional Representative listed below of all actions taken by your company to comply with this recall request. Within five (5) days of receipt of this letter, you should indicate to the EPA Regional Representative your agreement to comply with this recall request. At that time you will be instructed as to the specifics on conducting a recall, requirements for reporting on compliance with the recall, and how EPA intends to monitor the recall.

In addition, the Agency requires that you provide to the EPA Regional Representative listed below, within thirty (30) days of receipt of this letter, the following information concerning the production and distribution of the dicofol products listed above:

1. Inventory records, specifically all quantities currently in your company's control, ownership, or custody, and

2. Shipment records for the preceeding five months to include, by product:

   a. name and address of consignees,

   b. quantities shipped or delivered for shipment, and

   c. dates shipped or delivered for shipment.

The Agency will supervise your company's compliance with the records request, the Stop Sale, Use or Removal Order and this recall action through the office of the EPA Regional Branch Chief located in your area. The name, address, and telephone number of the EPA contact in your area is:

Mr. John Smith
U. S. Environmental Protection Agency
Hazardous Waste Management Division
Toxic and Pesticides Branch
841 Chestnut Street
Philadelphia, PA 19107
215-597-9870

If you have any questions regarding this letter, contact the Product Manager listed below immediately:

Lawrence J. Schnaubelt
Acting Product Manager (12)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Office of Pesticide Programs
401 M Street, S.W.
Washington, D.C. 20460
(703) 557-2386

Also enclosed is an Agency Stop Sale, Use, or Removal Order, effective immediately, which prohibits the further sale, distribution, or use of any dicofol product which was produced on or after June 29, 1986, which is under your control, ownership, or custody. As stated in the enclosed Stop Sale, Use, or Removal Order, any violation of the terms or provisions of the Order may result in the imposition of civil or criminal penalties as prescribed in section 14 of the Act.

Sincerely,

John A. Moore
Assistant Administrator
for Pesticides
and Toxic Substances

Attachment A - List of Cancelled Registrations

Attachment B - Stop Sale Use or Removal Order

Copy hand-delivered to Rohm & Haas Company at:

1667 K Street, N.W.
Washington, DC

Attachment A

PRODUCTS AFFECTED BY THIS NOTICE

Following is a list of your products affected by this Notice:

EPA Registration No.	Product Name
707-58	Kelthane W
707-59	Kelthane EC
707-66	Kelthane Dust Base - For Manufacturing Use Only
707-73	Kelthane MF
707-76	Kelthane AP
707-89	Kelthane 35 Agricultural Miticide Wettable Powder
707-107	Kelthane Technical
707-114	Kelthane Solution
707-119	Kelthane 60
707-164	Kelthane 4F

ATTACHMENT B

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

STOP SALE USE OR REMOVAL ORDER

24 SEP 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Rohm and Haas Company
Independence Mall West
Philadelphia, PA 19105
EPA Registration Numbers 707-58, -59, -66, -73, -76, -89, -107, - 119, -164

By the authority vested in me pursuant to Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. §136k(a)), you are hereby ordered not to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, receive and (having so received) deliver or offer to deliver, remove, or use the pesticides listed above, or any other pesticides under your control, ownership, or custody that were cancelled by operation of law, in accordance with the Notice of Intent to Cancel Registrations of Pesticide Products Containing Dicofol, which was published on May 29, 1986.

This order pertains to all quantities of the above-mentioned pesticides, which were produced on or after June 29, 1986, and which are within the control, ownership, or custody of your company, wherever located. The pesticides may not be sold, offered for sale, held for sale, shipped, delivered for shipment, received and (having so received) delivered or offered for delivery, removed or used other than in accordance with the provisions of this order or of further Stop Sale, Use, of Removal Orders as may be issued in connection with the pesticides.

Notwithstanding the provisions of this Stop Sale, Use, or Removal Order, you may ship any pesticides affected by this order which are under your control, ownership, or custody for purposed of consolidation in one or more locations, e. g., implementing a product recall.

Any person violating the terms or provisions of this order shall be subject to the civil or criminal penalties prescribed in Section 14 of the Act (7 U.S.C.§136l).

John J. Heylan III, Director
Compliance Division
Office of Compliance Monitoring

For further information concerning this Stop Sale, Use or Removal Order, contact:

Mr. John Smith
U. S. Environmental Protection Agency
Hazardous Waste Management Division
Toxic and Pesticides Branch
841 Chestnut Street
Philadelphia, PA 19107
215-597-9870