8-9-85

CASWELL FILE

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

AUG 9 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA #004001. Response to Industry Testing Proposal on Allethrin Data Call-In Notice

TO: Susan Lewis, PM Team #50 Tox. Chem No. 25
Registration Division (TS-767C)

FROM: Pamela Hurley, Toxicologist Pamela M. Hurley
Toxicology Branch
Hazard Evaluation Division (TS-769C) c. Trick 8/1/85

THROUGH: Edwin Budd, Section Head
Toxicology Branch
Hazard Evaluation Division (TS-769C) Budd 7/30/85

I.D. No. 004001
Record No. 153,145

Action Requested:

The Toxicology Branch has been requested to respond to a proposal submitted by Roussel Uclaf, dated June 11, 1985, concerning a data call-in notice on three of its allethrin formulations. The proposal requests that the long term testing requirements for the three formulations be satisfied by testing only one of the formulations as a representative of all three.

Response:

The Toxicology Branch has determined that before the Branch can adequately respond to Roussel's proposal, all the available subchronic data on the three formulations need to be collected and evaluated. Therefore, the Branch is requesting that the studies listed at the end of this memorandum be retrieved from EPA's existing files and/or from Roussel for our review.

Discussion:

The proposal concerns three chemical formulations of nearly identical components but of differing concentrations. Roussel proposes testing one formulation as a representative for all three. The long-term toxicity of the two major components of the formulations is unknown. Since subchronic data on either the components and/or on the three formulations may provide a fairly good indication of possible long-term toxicity, it is

1

necessary to review the available subchronic data on these chemicals before making a judgement as to whether or not chronic testing data on only one formulation is likely to provide sufficient information in support of the other formulations.

Roussel stated that they would be able to provide the EPA with copies of the studies that they listed in their proposal. The following list contains the studies which Roussel lists as in their possession that the Toxicology Branch would like to review for consideration of this proposal:

Bioallethrin

Ref. Report	Year	Country Where Study Done	Title
WELL-BA-72.16.02/A	1972	U.K.	Rat Oral 90 Day Tox. Study
IRDC-BA-406.034/A	1982	U.S.A.	Dog 6 Mo. Dietary Tox. Study
FDRL-BA-79.20.04/A	1979	U.S.A.	Terato. Evaluation of D. Trans Allethrin in S-Dawley Rats

S-Bioallethrin (ESBIOL)

OU-SB-75.05.27/A	1975	Japan	Subacute Inhalation in Mouse and Rat (1 month)
SU-SB-75.07.19/A	1975	Japan	3 Month and 6 Month Tox. Studies in Rats
CP-SB-75.02.28/A	1975	Japan	Terato. Results in Rats and Mice

The following list contains the studies from the EPA files that need to be retrieved and reviewed for this request:

Study/Lab/Study#/Date*	Material	EPA Accession No.	Document No.
90 Day Feeding - Rat Welcome Foundation 2/72	Allethrin (0.56%)	051098	002780
Chronic Inhalation Rat	Allethrin (1.0%)		002782
Chronic Inhalation Dog	Allethrin (1.0%)		002782
2 Yr. Feed. - Dog	Allethrin		002784
24 Wk Feed. - Rat Soap and Sanitary Chemicals 3/1950	Allethrin		002784

*Note: Many of these studies are very old. We are aware that it may be difficult to find them. Please keep us notified of your progress in locating them.

2

AUG 9 19

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

REISSUE OF ALLETHRIN DATA CALL IN NOTICE

Dear Registrant: 21 FEB 1985

It has come to our attention that the Data Call In Notice for products containing allethrin issued November 30, 1984, was not sent to some companies whose products contain different ratios of allethrin isomers such as d-trans allethrin or did not cover all of the allethrin products belonging to a particular company. As a result, we are reissuing this Data Call In Notice, to cover all products containing allethrin including those products with various ratios of the isomers found in allethrin. Therefore, the 90-day deadline of the November 30, 1984 Notice is extended to 90 days from receipt of this amendment rather than from receipt of the original Data Call In Notice. A copy of the original Data Call In Notice on allethrin is enclosed.

Because of the differences in isomeric ratios in allethrin products, the Agency proposes that registrants confer with one another to consider appropriate test material(s) for long term studies required to support continued registration. The recommendation(s) for test material(s) should be presented with their response to the Agency for consideration, together with supporting rationale.

Sincerely yours,

Robert V. Brown

Robert V. Brown, Deputy Director
Registration Division

3

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

30 NOV 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DATA CALL IN NOTICE FOR CHRONIC TOXICOLOGICAL DATA FOR ALLETHRIN

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing allethrin to submit certain data to the U.S. Environmental Protection Agency (EPA). Within 90 days after you receive this Notice you must inform EPA:

1. how you will comply with the data requirements set forth in this Notice; or

2. why you believe you are exempt from the requirements of this Notice; or

3. why you believe EPA should not require your submission of data in the manner specified by this Notice.

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration(s) of your product(s) subject to this Notice will be suspended. We have provided a list of all of your products subject to this Notice (Attachment A), as well as a list of all registrants who have received this Notice (Attachment B).

The authority for this Notice is §3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136a(c)(2)(B).

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency is including in this Notice the chronic data needs usually requested as a part of the ongoing regular Data Call In Program. Since this chemical is included in products used on food, it would be subject normally to chronic testing requirements. These tests are also required for certain non-food uses. We have not examined in detail the use patterns for your product(s). If your product(s) is not used for food or other uses subject to the chronic testing requirements of the Pesticide Registration Guidelines, see Section III-C for instructions on submitting a request that the guidelines do not apply to your product(s). A copy of the "When Required" portion of the chronic testing requirements of those Guidelines is attached for use in your evaluations. (Attachment C). The existing chronic data in the areas of chronic feeding, oncogenicity, reproduction and teratology (the traditional areas included in Data Call In) are cited in a list included as Attachment B-1. Therefore, the Agency imposes the requirement to supply the remaining chronic data needed. If there are any additional existing chronic studies in this area, please let us know.

All the data we are requiring are called "generic" data. They pertain to the safety of that active ingredient in all products having the use patterns for which the data are required.

SECTION II. DATA REQUIRED

II-A Toxicological Data Needed:

These data are specified in the Proposed Data Requirements, section 158.135, toxicology data requirements, chronic testing.

1. Chronic Feeding Study(s).

   Data needed: A chronic feeding study in two species.

2. Oncogenicity Study(s).

   Data needed: An oncogenicity study in two species.

3. Reproduction Study(s).

   Data needed: A reproduction study in one species.

4. Teratogenicity Study(s).

Data needed: No additional data needed at this time.

II.-B. Schedules for Submission of Data

The chronic studies must be submitted according to the following schedule:

1. Chronic Feeding Study(s) in two species.

- A progress report is due 8 months after receipt of this Notice and semiannually thereafter.
- A final report is due 48 months after receipt of this Notice.

2. Oncogenicity Study(s) in two species.

- A progress report is due 8 months after receipt of this Notice and semiannually thereafter.
- A final report is due 48 months after receipt of this Notice.

3. Reproduction Study(s) in one species.

- A progress report is due 8 months after receipt of this Notice and semiannually thereafter.
- A final report is due 48 months after receipt of this Notice.

II-C. Testing Protocols

Any studies to be conducted and submitted under Section II-A must be conducted in accordance with acceptable test standards such as those outlined in the Pesticide Assessment Guidelines. Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable provided that the test duration, degradate identification, (environmental fate) requirements, and selection of test species conform to that specified in the proposed Pesticide Data Requirements regulation (Part 158.70). The Pesticide Registration Guidelines were proposed by EPA in the Federal Register (FR) on August 22, 1978, 43 FR 37336. Subsequently, the registration data requirements were summarized as a proposed regulation on November 24, 1982, 47 FR 53192 (40 CFR Part 158) and the final data requirements regulation was published on October 24, 1984 (49 FR 42856). The final regulation is labeled "Data Requirements for Pesticide Registration:

Final Rule." The Pesticide Assessment Guidelines contain recommendations concerning the standards for conducting acceptable tests and other guidance and appear in Subdivision O the Residue Chemistry Guidelines, chemistry studies in Product Chemistry in Subdivision D, and Environmental Fate in Subdivision N and the chronic toxicology data requirements are in Subdivision F - Hazard Evaluation; Humans and Domestic Animals. These EPA Guidelines are available as: NTIS Order No. PB83-153916; for Subdiv. F (hard copy $16.00/microficne $4.50); PB83-153890 for Subdiv. D ($11.50); PB83-153973 for Subdiv. N ($13.00); and PB83-153981 for Subdiv. O ($10.00); from the National Technical Information Service (NTIS), Att: Order Desk, 5285 Port Royal Rd., Springfield, VA 22161 (703-4874650). The OECD protocols are available from OECD, 1750 Pennsylvania Ave., N.W., Washington, D.C. 20006.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

Within 90 days of receiving this Notice, you must submit for each of your products subject to this Notice a completed copy of the "Data Call In Summary Sheet" (Attachment C). On that sheet you must state which option(s) you have selected to comply with this Notice. At the same time, you must also submit any additional documents required to support the option(s) chosen. The Summary Sheet and other attachments are provided to assist you in responding to this Notice. Do not alter the printed material. If you believe you qualify for more than one of the available options provided by this Notice, you should choose every option for which you believe you may qualify when you respond to this Notice. In processing responses which specify more than one option for complying with this Notice, EPA will attempt to adopt the option which will impose the least burden on the registrant.

SECTION III-A EXEMPTION FROM THE REQUIREMENTS OF THIS NOTICE

Generic Data Exemption -- Under §3(c)(2)(D) of FIFRA, an applicant for registration of an end-use product is exempt from the requirement to submit or cite data concerning an active ingredient if he intends to formulate his product from a purchased registered pesticide product containing the active ingredient. EPA has concluded that such an end-use registrant also should normally be exempt from a §3(c)(2)(B) notice requiring data on the active ingredient which they purchase. To qualify for this exemption all of the following requirements must be met.

1. Your registration must be for an end-use product;

2. The allethrin in your product must be present solely because of incorporation (during formulation or packaging) of another registered product which contains allethrin;

3. Every registrant who is the ultimate source of the allethrin in your product must be in compliance with the requirements of this Notice and must remain in compliance; and

4. You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the generic data exemption you must submit a completed Generic Data Exemption Statement (Attachment D) and all supporting documentation for each of your products for which you claim the exemption.

Exemption for low volume minor use pesticides -- Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume minor use pesticides. In implementing this provision EPA considers as a low volume chemical only active ingredients whose total production volume for all manufacturers is small. If the active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing.

To apply for a low volume minor use exemption, you must submit the following information:

1. Your total production in pounds per year of allethrin for all uses (including non-pesticide uses) of the chemical for each of the last five calendar years.

2. A listing of all uses of the allethrin you produce and the amount used in pesticide products.

3. A financial impact analysis which treats the cost of the proposed testing and addresses the ability to pass those costs on to the users of the product.

4. Statement of how important allethrin is to users.

5. A list of data requirements for which you request an exemption and a detailed explanation of why an exemption is requested.

SECTION III-B PRODUCTION OF DATA REQUIRED BY THIS NOTICE

There are three methods by which you may meet the requirements of this Notice to produce data. First, you may commit to the Agency that you will develop the data. Second, you may share in the cost of developing the data. Third, you may submit existing data which satisfies the requirements of this Notice.

If you choose to develop the required data yourself or to submit existing data, within 90 days of receipt of this Notice you must submit a completed Data Coversheet for each study to be provided.

Submitting Existing Data -- If you submit existing data you must include two copies of the study. You must also determine that the data satisfy one or more of the requirements imposed by this Notice. If the data do not, you still will be required to comply with this Notice, normally without any extension of the required date of submission.

Developing Data -- If you choose to develop the required data, your submission should also indicate the protocols to be followed in conducting the study. If you wish to use a protocol which differs from the options provided by Section II of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose not to accept a protocol not specified in Section II; rejection of the proposed protocol will not be a basis for any extension of time for submission of data.

Sharing Cost to Develop Data -- If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

SECTION III-C OTHER COURSES OF ACTION UNDER THIS NOTICE

There are additional options available in responding to this Notice. First, you may claim that one or more data requirements should not apply to your product. Second, you may amend your registration to delete the uses to which one or more data requirements apply. Third, you may ask for the voluntary cancellation of your registration. Fourth, you may request that EPA use its discretion and not suspend your registration because of your good faith efforts.

Applicable Data Requirements -- If the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to Section 3(c)(2)(B). If you claim that the data requirements are not applicable to your product(s), you must submit an explanation of why you believe they do not apply. You should also submit the current label(s) of your product(s) and a copy of the Confidential Statement of Formula of the product(s). IF EPA determines that the data are required for your product(s), you must choose another method of meeting the requirements of this Notice in a timely manner.

Voluntary Cancellation or Amendment -- You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirement applies. To do so you may choose either to voluntarily cancel your registration or to seek amendment of the registration to delete the appropriate uses. If you wish to amend your registration, you must submit a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application.

Discretionary Non-Suspension of your Registration(s) -- You may also request EPA to exercise its discretion not to suspend your registration(s) although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy it will not suspend the registration of a product if the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program but the other registrant(s) developing the data have refused to accept his offer. In order to qualify for this option you must prove to EPA that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also provide us with a copy of that offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing

agreement to be bound by binding arbitration as provided by FIFRA Section 3(c)(2)(B)(iii). In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement. The other registrant must also inform us on a Summary Sheet that he will develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice.

SECTION III-D EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

If your product is cancelled or suspended as a result of this Notice, EPA has the authority to permit continued sale and distribution of existing stocks of the product(s). If you expect to have your product suspended or intend to voluntarily cancel your registration, and if you desire to continue to sell and distribute existing stocks, you must request an existing stocks provision. Any such request must include an explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their use.

SECTION IV INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, please contact: Susan Lewis or Alan Hill (703) 557-7460.

All responses to this Notice must include a completed Data Call In Summary Sheet and the other documents required by Section III of this Notice, and should be submitted to:

Geraldine W. Werdig, Chief
Data Call In Program
Registration Division (TS-767)
U.S. Environmental Protection Agency
401 M Street, SW.,
Washington, DC 20460

RE: Allethrin

Sincerely yours,

Robert V. Brown

Robert V. Brown, Deputy Director
Registration Division

11

Attachment A = List of Registrant's Products Containing Allethrin
" B = List of Registrants With Products Containing Allethrin
" B-1 = List of Existing Chronic Data
" C = Data Call In Summary Sheet for Chronic Data
" C-1 = Chronic Testing Requirements of Pesticide Registration Guidelines
" D = Generic Data Exemption Statement and Confidential Statement of Formula
" E = Coversheet for Submitting Data

ATTACHMENT B

0004	BONIDE CHEMICAL CO. INC.	2 WURZ AVE.	YORKVILLE NY	13495
0016	DRAGON CHEMICAL CORP	PO BOX 7311	ROANOKE VA	24019
0052	WEST CHEMICAL PROD INC	8 WEST 40TH ST.	NEW YORK, NY	10018
0070	RIGO COMPANY, INC.	P.O. BOX 98	BUCKNER, KENTUCKY	40010
0099	WATKINS PRODUCTS INC	150 LIBERTY ST	WINONA MN	55987
0192	DEXOL INDUSTRIES	1450 W 228TH ST	TORRANCE CA	90501
0201	SHELL CHEMICAL COMPANY	1025 CONNECTICUT AVE N.W. SUITE 200	WASHINGTON, D.C.	20036
0239	CHEVRON CHEMICAL COMPANY	940 HENSLEY STREET	RICHMOND CA	94804
0257	CELLO CORPORATION	1354 OLD POST ROAD	HAVRE DE GRACE MD	21078
0270	FARNAM COMPANIES INC	2230 EAST MAGNOLIA	PHOENIX, ARIZONA	85036
0334	HYSAN CORPORATION	919 W 38TH ST	CHICAGO IL	60609
0419	ACME BURGESS, INC.	ROUTE 83	GRAYSLAKE, IL.	60030
0432	PENICK CORPORATION	1050 WALL STREET WEST	LYNDHURST, NEW JERSEY	07071
0464	DOW CHEMICAL U S A	PO BOX 1706	MIDLAND MI	48640
0475	BOYLE-MIDWAY INC	S AVE & HALE ST	CRANFORD NJ	07016
0478	REALEX CORP.	BOX 78 2500 SUMMIT ST.	KANSAS CITY MO	64141
0485	INDUSTRIAL FUMIGANT COMPANY	601 EAST 159TH ST.	OLATHE, KS	66061
0491	SELIG CHEMICAL INDUSTRIES THE	840 SELIG DR P.O. BOX 43106	ATLANTA GA	30378
0498	CHASE PRODUCTS COMPANY	19TH ST AND GARDNER ROAD	BROADVIEW IL	60153
0499	WHITMIRE RESEARCH LABS INC	3568 TREE CT INDUSTRIAL BLVD	ST LOUIS MO	63122
0506	WALCO LINCK CORP.	P.O. BOX 769	CLIFTON, NJ	07015
0541	PURITAN/CHURCHILL CHEMICAL CO.	PO BOX 93247 MARTECH STATION	ATLANTA GA	30318
0622	NORDEN LABS INC	601 W CORNHUSKER	LINCOLN NE	68521
0654	FEDERAL CHEMICAL COMPANY INC	5820 WEST 85TH ST.-SUITE 101	INDIANAPOLIS, IN.	46278
0655	PRENTISS DRUG & CHEMICAL COMPANY INC	C.H. 2000	FLORAL PARK, N.Y.	11001
0665	CLEVELAND CO	WATERLOO IA		
0713	ATLAS MANUFACTURING COMPANY	BOX 224969-2321 BEATRICE ST.	DALLAS TX	75264
0729	GULF OIL CORP	PO BOX 1166	PITTSBURG,PA	15230
0769	SECURITY CHEMICAL COMPANY	270 CARPENTER DRIVE SUITE 460	ATLANTA, GA	30328
0778	CONSUMER PRODUCTS DIV. A.H. ROBINS CO. I	3800 COTSHAW AVE.-P.O. BOX 6235	RICHMOND, VA	23230
0784	CONSOLIDATED CHEM INC	3224 SOUTH KINGSHIGHWAY BLVD.	ST LOUIS, MO	63139
0861	UNCLE SAM CHEMICAL COMPANY INC	575 W 131ST ST	NEW YORK NY	10027
1021	MCLAUGHLIN GORMLEY KING CO	8810 TENTH AVE NORTH	MINNEAPOLIS,MINNESOTA	55427
1187	VIRGINIA CHEM INC	3340 W NORFOLK RD	PORTSMOUTH VA	23703
1193	707 COMPANY	1530 STILLWELL AVE	BRONX NY	10461
1221	BARTLETT CHEMICALS INC	4955 RIVER ROAD, P.O. BOX 10710	JEFFERSON, LA	70181
1266	MALTER INTERNATIONAL CORPORATION	PO BOX 6099	NEW ORLEANS LA	70174
1270	ZEP MANUFACTURING COMPANY	1310 SEABOARD INDUSTRIAL BLVD. NW	ATLANTA,GEORGIA	30318
1325	WEIL CHEMICAL COMPANY	219 SCOTT STREET	MEMPHIS, TN	38112
1421	THE DETTELBACK CHEMICAL CORP.	2676 APPLE VALLEY RD. NE	ATLANTA, GA	30319
1537	CENTER CHEMICAL COMPANY	BOX 80202	ATLANTA GA	30341
1553	HOMAR INC	PO BOX 19567 STATION N	ATLANTA GA	30325
1603	HEFFER-GALLER WORKS	4044 PARK AVENUE	ST. LOUIS, MO.	63110
1604	GALREE PROD CO SUBSID	300 PK AVE	NEW YORK NY	10022
1622	KITX CHEMICAL COMPANY	551 RAILROAD AVE	SOUTH SAN FRANCISCO, CA	94080
1645	KNOX CHEMICAL CO.	7625 PAGE BLVD.	ST. LOUIS, MO.	63133
1663	GRANT LAB. DIV.	6020 ADELINE ST.	OAKLAND CA	94608
1748	YORK CHEMICAL CO., INC.	118 FULTON AVE.	GARDEN CITY PARK NY	11040
1769	MANTEK	1590 E. NORTHGATE	IRVING, TX	75062
1783	TRIO CHEMICAL WORKS INC	341-347 SCHOLES ST	BROOKLYN NY	11206
2019	GASTON JOHNSTON CORP.	1919 LONE STAR DRIVE	DALLAS, TX	75212
2097	BEECHAM LABORATORIES	513-529 5TH ST	BRISTOL TN	37620
2155	I. SCHNEID, INC.	BOX 93188-MARTECH STATION	ATLANTA GA	30318

2270	HUGE COMPANY, INC., THE	7625 PAGE AVE	ST. LOUIS, MO	63133
2393	HOPKINS AGRICULTURAL CHEMICALS	537 ATLAS AVE. PO BOX 7532	MADISON, WI	53707
2596	HARTZ MOUNTIAN CORP	700 SO 4TH ST	HARRISON NJ	07029
2915	FULLER BRUSH COMPANY THE	P.O. BOX 729 WESTPORT ADDITION	GREAT BEND, KS	67530
3060	KOTAKE COMPANY LTD	P O BOX 3512- 439 NIMITZ HIGHWAY	HONOLULU, HI	96817
3095	PIC CORPORATION	23 SOUTH ESSEX AVE.	ORANGE, N.J.	07050
3181	AERO MASTER INC	325 W PACIFIC AVE	ST LOUIS MO	63119
3282	D-CON COMPANY INC	225 SUMMIT AVENUE	MONTVALE, N.J.	07645
3298	MURO COMPANY	1824 N. HANCOCK ST.	PHILADELPHIA, PA	19122
3314	COLONIAL PRODUCTS INC	1830 TENTH AVENUE NORTH	LAKE WORTH FL	33461
3367	REGENCY CHEMICAL COMPANY/REILY CHEMICAL	450 MANDEVILLE STREET-P.O. BOX 50372	NEW ORLEANS, LA	70117
3407	FULD-STALFORT, INC	1354 OLD POST ROAD	HARVE DE GRACE, MD	21078
3624	NOVA PRODUCTS INC	800 HICKORY	KANSAS CITY, MISSOURI	64101
3635	OXFORD CHEMICALS	PO BOX 80202	ATLANTA GA	30366
3696	TEXIZE DIV. OF MORTON THIKOL, INC.	BOX 368	GREENVILLE, SC	29602
4000	SOUTHERN CHEMICAL PRODUCTS COMPANY	PO BOX 205	MACON GA	31202
4077	ORR INDUSTRIES INC	#2 RACE ST (BOX 1067)	UPLAND PA	19015
4206	BARCOLENE COMPANY THE	620 SOUTH ST	HOLBROOK MA	02343
4476	MORTON PHARMACEUTICALS INC	1625 N. HIGHLAND ST./P.O. BOX 8037	MEMPHIS TN	38108
4584	GEM INC	#1 GEM BLVD	BYHALIA, MS	38611
4726	BUSTER'S INC	PO BOX 1299	BRAWLEY CA	92227
4816	FAIRFIELD AMERICAN CORPORATION	8TH AND HARRISON ST.	FRENCHTOWN, NEW JERSEY	08825
4822	S.C. JOHNSON & SON INC.	1525 HOWE STREET	RACINE, WI	53403
4887	STEPHENSON CHEM COMPANY INC	BOX 87188	COLLEGE PARK GA	30337
4925	KING CHEMICALS CO LTD	NO 1 MINAMI 3-CHROME OYODO-CHO	OSAKA JAPAN	
4972	PROTEXALL PRODUCTS INC.	1109-11 HWY 427 N.	LONGWOOD, FL.	32750
4990	JET-AER CORPORATION	100 SIXTH AVE	PATERSON NJ	07524
5086	ROUSSEL CORP	155 E 44TH ST	NEW YORK NY	10017
5130	JOHNSON CHEMICAL COMPANY	227 JOHNSON AVE	BROOKLYN NY	11206
5197	KEM MFG CORP	2075 TUCKER INDUSTRIAL RD.	TUCKER,GA.	30084
5440	CARDINAL CHEMICAL COMPANY	50 FRANCISCO ST.	SAN FRANCISCO CA	94133
5590	ATI RESEARCH CENTER	OLD GATE LANE	MILFORD CT	06460
5693	SHIELD CHEMICAL CO INC	21 UNIVERSITY RD	CANTON, MA	02021
5719	CHACON CHEMICAL CORP	2600 YATES AVENUE	CITY OF COMMERCE, CA	90040
5736	DUBOIS RESEARCH LABORATORIES	3630 E. KEMPER	SHARONVILLE OH	45241
5748	CONWOOD CORPORATION	P.O. BOX 217	MEMPHIS TN	38101
5769	UNION CARBIDE CORP	BLDG 1 OLD SAW MILL RIVER ROAD	TARRYTOWN, NY	10591
5887	BLACK LEAF PRODUCTS COMPANY	667 N STATE ST	ELGIN IL	60120
5927	DACUS INC	HIGHWAY 6 WEST PO DRAWER 528	TUPELO MS	38801
6129	MCGRAW EDISON COMPANY	1701 W. GOLF ROAD 1 CONTINENTAL TOWERS	ROLLING MEADOWS IL.	60008
6175	HART-DELTA INC	5055 CHOCTAW DR	BATON ROUGE LA	70805
6218	SUMMIT CHEMICAL COMPANY	7657 CANTON CENTER DR.	BALTIMORE MD	21224
6330	INTERNATIONAL DIATOMS INDUSTRIES, LTD	904 WEST 23RD	YANKTON, SD	57078
6529	HATA & COMPANY LTD Y	BOX 1348	HONOLULU HI	96807
6607	HATESVILLE CHEMICAL COMPANY	205 PAMELA ST	HATESVILLE MS	38606
6718	AMWAY CORPORATION	7575 E FULTON RD	ADA MI	49355
6723	HFD WING CHEMICAL COMPANY INC	920 MCCALLIE AVENUE	CHATTANOOGA TN	37403
6755	FUJII SHOJI LTD	1180 KONA ST	HONOLULU HI	96814
6899	B & B CHEMICAL COMPANY INC	875 W 20TH ST	HIALEAH FL	33010
6993	GERMAINS INC	4820 E 50TH ST	LOS ANGELES CA	90058
7056	CSA, LIMITED, INC.	P.O. BOX 73308	HOUSTON TX	77273
7173	CHEMPAR CHEMICAL COMPANY INC	60 EAST 42ND ST. - SUITE NO. 650	NEW YORK, N.Y.	10165
7286	STEERS CHEM INC	112-116 W JACKSON	IOLA KS	66749

305	NISHIMOTO TRADING COMPANY LTD	C/O SUITE 1412 AMTAC BLDG-700 BISHOP STR	HONOLULU, HI	96813
368	GEORGIA-PACIFIC CORPORATION	760 S. VAIL AVENUE	MONTEBELLO, CA	90640
605	CHEMICAL PACKAGING CORP	PO BOX 9947	FT LAUDERDALE FL	33310
502	ROMANO, H. J.	BOX 1901	OLD SAN JUAN STATION P R	00803
710	TIME-MIST	835 S. MAIN ST.	WATERBURY, CT.	06720
754	ANIMAL REPELLENTS INC.	P.O. BOX 999	GRIFFIN, GA	30224
768	DE JESUS TRADING COMPANY	CARPENTER RD 745	SANTURCE PR	00907
385	ZOE CHEMICAL COMPANY	1801 FALMOUTH AVE	NEW HYDE PARK NY	11040
092	T N T CHEMICALS INC	7301 NW 77TH ST	MIAMI FL	33166
112	LION INSECTICIDE COMPANY LTD	8-10 FUKUSHIMA 6 CHOME FUKUSHIMA-KU	OSAKA 553 JAPAN	07627
123	MILLER FRANK & SONS INC	13831 SO EMERALD AVE	CHICAGO IL	60627
550	PRO - SPECIALTIES, INC.	7754 W. HARWOOD AVENUE	WAUWATOSA,WI	53213
590	AGWAY, INC.-CROP SERVICES	BOX 4741	SYRACUSE NY	13221
512	B & G COMPANY	10539 MAYHANK DR P.O. BOX 20372	DALLAS TX	75220
598	ST AUBREY ASSOCIATES DIV EIGHT IN ONE PR	100 EMJAY BLVD	BRENTWOOD NY	11717
848	SAFEGUARD CHEMICAL CORP	806 E. 144 ST.	BRONX NY	10454
075	PENGUIN DOWN CO.	6520 NANA	MIRALOMA CA	91752
086	HOXO EXPORTS INC	10 COTTAGE PL	NEW ROCHELLE NY	10802
143	CHEMSCOPE CORP	3200 F. RANDOL MILL RD.	ARLINGTON, TX.	76011
622	A&H ENTERPRISES, INC.	12917 HITNEY SPRINGS RD.	NEVADA CITY, CA	95959
644	CLINE-BUCKNER INC	14317 PIUMA AVE	CERRITOS CA	90701
591	NATIONWIDE CHEMICAL PRODUCTS INC	P. O. BOX 3027	HAMILTON OH	45013
588	CHEMSICO INCORPORATED	8494 CHAPIN INDUSTRIAL DRIVE	ST LOUIS, MO	63114
171	MAIUKAI HAWAII INCORPORATION	1311 KILANI ST	HONOLULU, HI	96817
292	VENUS LABORATORIES, INC.	855 LIVELY BLVD	WOOD DALE, IL	60191
870	FORDS CHEMICAL AND SERVICE INC.	2739 PASADENA BLVD.	PASADENA, TX.	77502
623	ESSEX CHEMICAL CORPORATION	CONNAIR ROAD	ORANGE, CT	06477
583	GENERAL CONTROL COMPANY INC	3334 E. PENNSYLVANIA ST.	TUCSON, AZ.	85714
728	COLEMAN COMPANY INC THE	250 NO. ST. FRANCIS STREET	WICHITA KS	67201
806	CONTACT INDUSTRIES INC	641 DOWD AVENUE	ELIZABETH, NJ	07201
807	AMREP, INC.	945 E. PLEASANT RUN RD.	LANCASTER, TX	75146
000	SPRAYON PRODUCTS INC.	26300 FARGO AVE.	BEDFORD HEIGHTS, OHIO	44146
166	DOUGLAS VETERINARY PRODUCTS INC	3600 TROOST AVE	KANSAS CITY MO	64109
174	SUNGRO CHEMICALS, INC.	P. O. BOX 24632	LOS ANGELES, CA.	90024
525	PETERSON PURITAN INC	HEGELER LANE	DANVILLE IL	61832
583	DOUGLAS PHARMACAL INDUSTRY INC	3600 TROOST AVE	KANSAS CITY MO	64901
592	CHEMURGY MANUF CORP.	BOX 34223	DALLAS TX	75234
598	CONNECTICUT AEROSOL INC	85 FURNITURE ROW	MILFORD, CO	06460
523	APOLLO INDUSTRIES INC.	1850 SOUTH COBB INDUSTRIAL BLVD.	SMYRNA, GA	30080
594	DYMON, INC.	3401 KANSAS AVENUE	KANSAS CITY, KS	66106
715	SPEER PRODUCTS INC	PO BOX 18993-4242 H F GOODRICH BLVD	MEMPHIS TN	38118
050	CHEMCO CHEMICAL COMPANY	P.O. BOX 40185	DALLAS, TX	75001
330	TOMLYN PRODUCTS	1800 EAST NORTH PARK ST.	OKEECHOBEE, FL	33472
799	FOUR PAWS PRODUCTS LTD	200 OVAL DRIVE	CENTRAL ISLIP, N.Y.	11722
991	ACCRA PAC INC	P.O. BOX 878	ELKHART, IN	46515
998	CONTRACT PACKAGING INC	1733 GRAND AVE.	DES MOINES, IOWA	50309
864	KASSNAR IMPORTS INC	PO BOX 3895	HARRISBURGH PA	17105
524	NIPPON KODO INC	220 FIFTH AVE	NEW YORK NY	10001
384	JRS INTERNATIONAL ASSOCS LTD	19 W. 44TH STREET	NEW YORK, NEW YORK	10036
165	CHEM-I-MATIC INC	3548 EAST T.C. JESTE BLVD.-P.O. BOX 1070	HOUSTON TX	77018
050	COBRA INTERNATIONAL INC	PO BOX 985	BAYAMON PR	00619
708	SHIELD AEROSOL COMPANY OF CALIFORNIA	5165 G STREET	CHINO, CA	91710
309	CARDINAL LABORATORIES INC	710 S. AYON AVE.	AZUSA, CA.	91702

G1

3	WRIGHT WEBB CORP	PO BOX 1572	FORT MYERS FL	33902
3	LFA CHEMICALS	PO BOX 868	MARIANNA FL	32446
6	MOL INDUSTRIES INC.	3600 WEST CARRIAGE DR	SANTA ANNA, CA.	92704
4	AEROSOL SERVICES CO INC	425 S 9TH AVE	CITY OF INDUSTRY, CA	91746
5	PAT GORDON CORP	1217 WEST 12TH STREET	KANSAS CITY, MO	64101
4	CHEMETTE CORP	12600 S DAPHNE	HAWTHORNE, CA	90250
8	WINCO CHEMICAL COMPANY	P.O. BOX 10692	JACKSON, MS	39209
6	ENTERPRISE SALES CO.	919 EAST THIRD ST.	LOS ANGELES, CA	90013
4	KONA-RAD PRODUCTS, INC.	501 SOUTH HASINGER RD.	PANDORA, OH	45877
6	EUREKA LABORATORIES, INC.	2033 W FULTON ST	CHICAGO IL	60612
5	ADAMS VETERINARY RESEARCH LABS, INC	P.O. BOX 971039	MIAMI, FL	33197
4	PACE LIMITED	P.O. BOX 48	TAYLOR, TEXAS	76574
4	ARCHEM, INCORPORATED	P.O. BOX 1122	CONWAY, AR	72032
1	FALLS CHEMICALS INC	P.O. BOX 2345	GREAT FALLS, MT	59403
9	C R J CHEMICAL	P.O. BOX 1068	CARTERSVILLE, GA	30120
5	DERMATOLOGICS FOR VETERINARY MEDICINE, I	8785 N.W. 13TH TERRACE	MIAMI, FL	33172
9	CHEMICAL SPECIALTIES MFG. CO.	829 WEST MAIN ST.	MESA, AZ	85201
0	SOUTHEAST PACKAGING CORP	701 WHARTON CIRCLE SW	ATLANTA, GA	30336
2	PETROFAX INTERNATIONAL	1545 MARIETTA BLVD, N.W.	ATLANTA, GA	30318
6	P.E.L. ASSOCIATES, INC.	30-3 FARM RD.	SOMERVILLE, N.J.	08876
7	INDUSTRIE CHIMICHE ZO BELESPA	38100 VIA MUREDEI, 2-4	TRENTO, ITALY	00000
4	STEWART SANITARY SUPPLY CO., LTD.	P.O. BOX 15061	ST. LOUIS, MO.	63110
0	ARMIS CO.	919 WEST 38TH ST.	CHICAGO, IL.	60609
4	TESTRON	1310 GRESHAM RD. N.E.	MARIETTA, GA	30062
5	CHEM-TOX, INC	21 N. 9HH PEPPER RD,	BARRINGTON, IL	60010
1	AERDFILL, INC.	7 TURNER PLACE	PISCATAWAY, NJ	08854
3	ALLERDERM INC.	P.O. DRAWER 277	HURST, TX	76056
3	CCL INDUSTRIES INC.	235 YORKLAND BLVD, STE. 500	WILLOWDALE, ONTARIO M2 J	00000
0	CHEM-TECH, LTD	1727 HULL AVE.	DES MOINES, IA	50313
6	TUXIS CORP, LTD	111 BRADLEY RD	MADISON, CT	06443
4	HEARTLAND INDUSTRIES INC.	BOX 687	WALNUT, CA	91789
8	INSAO S.P.A INTERNATIONAL SALES ORGANIZA	VIA ZANELLE 4873	MILAN, ITALY	00000

191 RECORDS PRINTED

ATTACHMENT B-1

EXISTING CHRONIC TOXICOLOGICAL DATA IN EPA FILES FOR ALLETHRIN

1. Chronic Feeding Study(s) (two species).

   Data located in EPA files are: None.

2. Oncogenicity Study(s) (two species).

   Data located in EPA files are: None.

3. Reproduction Study.

   Data located in EPA files are: None.

4. Teratogenicity Study(s) (two species).

   Data located in EPA files are:

   Teratologic Evaluation of D-trans Allethrin in Sprague-Dawley Rats by M. Knickerbocker and T. A. Re; report #6059; report date 1979; performed by Food and Drug Research Laboratories; submitted to Shell Chemical Corp.; MRID #78624; EPA Acces. #238638-A.

   Final Report: Teratology Study - Rabbits by W. M. Weatherholtz; report #343-109; report date 1972; performed by Hazleton Laboratories, Inc.; submitted to Sumitomo Chemical Co., Ltd.; MRID #90522; EPA Acces. #234587-O.

ATTACHMENT C DATA CALL-IN SUMMARY SHEET

EPA Registration No.: _____
Product Name: _____
Registrant's Name: _____
Date of Data Call-In Notice: _____ for products containing _____ as an active ingredient.

Note: For each registered product, a separate "Data Call-In Summary Sheet" must be filled in and sent to the Agency. If you qualify for a "generic" data exemption or have decided to voluntarily cancel/suspend your registration, check the appropriate box for Nos. 1 or 2.

1. A. ☐ I request a voluntary cancellation of this product's registration.

1. B. ☐ I request a FIFRA Section 3 Notice of Intent to Suspend this product's registration.

2. ☐ I request an end-use exemption. Attached is a current, accurate Confidential Statement of my product's composition indicating my source of active ingredient or a certification on the "Generic Data Exemption Statement."

If you select only Option 1 or 2 above, sign here, and return this page to EPA.

Dated _____ _____
Signature of Authorized Representative

_____ _____ _____
Telephone No. + area code | Name Typed or Printed | Address if different from mailing address

If you choose one or more of the following options (Nos. 3-12), you may choose different options for different data requirements, but for each data requirement, at least one box must be checked.

Options Nos. 3-5 for satisfying Notice's data requirements	Chronic Feeding		Oncogenicity		Teratogenicity		Reproductive
	Species #1	Species #2	Species #1	Species #2	Species #1	Species #2	
3. I am submitting existing data for each data requirement box which has been checked. A cover sheet (Attachment F) is attached which summarizes each study submitted.							
4. I will generate and submit data for each data requirement box which has been checked and submit progress reports according to the schedule in Section II. B. of this Notice. These data will be generated according to the Pesticide Registration: Proposed Data Requirements regulation ☐, the OECD protocols ☐, or different protocol ☐. A completed coversheet (Attachment E) is attached.							
5. I have entered into an agreement under FIFRA 3(c)(2)(B)(ii) with one or more other Registrants to share the burdens of generating and submitting data and progress reports for each data requirement box which has been checked according to the schedule in Section II. of this Notice A copy of the agreement is attached and the name and address of registrant to							

Other Options 6 through 9	Chronic Feeding		Oncogenicity		Teratogencity		Reproductive
	Species #1	Species #2	Species #1	Species #2	Species #1	Species #2	
6. I claim that I am not obliged to arrange to submit the data required by this Notice for the following checked data requirement box(es) because the use(s) of my registered pesticide product are such that, under the Pesticide Registration: Proposed Data Requirements regulation, these data requirements do not apply to my product. Attached is an explanation of why my registered pesticide product is not subject to the Requirements together with a current and accurate Confidential Statement of my product's composition and current label for my registered pesticide product.							
7. I enclose a completed application to amend my registration by deleting one or more of its currently registered uses. Once this amendment is approved, I believe the data requirements in the checked box(es) will not apply to my product.							
8. I request a waiver from the obligation to arrange to submit data for the following checked data requirement box(es), because the active ingredient in my registered, pesticide product is a low volume/minor chemical. Attached are the documents necessary for a low volume/minor chemical request according to Section III.							
9. I have submitted an offer as specified in Section III of the Notice but have been unsuccessful in entering into any agreement to share the burdens of generating data with other registrant(s) who is committed to generate the data. Attached are copies of the offers I have made regarding the requirements indicated by the checked data box(es). Also attached is proof of receipt of the offer(s).							

Dated

Signature of Authorized Representive

Typed or Printed

Telephone No. + area code

Address (If different from address)

ATTACHMENT C-1

§ 158.135 Toxicology data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the toxicology data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns: Terrestrial: Food crop	Terrestrial: Nonfood	Aquatic: Food crop	Aquatic: Nonfood	Greenhouse: Food crop	Greenhouse: Nonfood	Forestry	Domestic outdoor	Indoor	Food substances in: Data to support MP	Data to support EP	Guideline reference No.
Acute testing:													
Acute oral toxicity—rat	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP or EP diluted and TGAI	81-1
Acute dermal toxicity	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP or EP diluted and TGAI	81-2
Acute inhalation toxicity—rat	(19)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP and TGAI	81-3
Primary eye irritation—rabbit	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	81-4
Primary dermal irritation	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	81-5
Dermal sensitization	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	81-6
Acute delayed neurotoxicity—hen	(4)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	81-7
Subchronic testing:													
90-day feeding studies—rodent and nonrodent	(17)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	82-1
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI and EP	82-2
90-day dermal	(5), (19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-3
90-day inhalation—rat	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-4
90-day neurotoxicity:													
Hens	(7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-5
Mammals	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-6
Chronic testing:													
Chronic feeding—2 spp: rodent and nonrodent	(9), (13), (20)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83-1
Oncogenicity study—2 spp. rat and mouse preferred	(9), (21)	R	CR	R	CR	R	CR	CR	CR	CR	TGAI	TGAI	83-2
Teratogenicity—2 species	(10), (15)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83-3
Reproduction, 2-generation	(11), (14)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83-4
Mutagenicity testing:													
Gene mutation	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84-2

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Structural chromosomal aberration	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84-2
Other genotoxic effects	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84-4
Special testing													
General metabolism	(23)	R	CR	R	CR	R	CR	CR	CR	CR	PAI or PAIRA	PAI or PAIRA	85-1
Dermal penetration	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choice	Choice	85-2
Domestic animal safety	(12)	CR	CR	CR	CR			CR	CR		Choice	Choice	86-1

Key: R = Required data; CR = Conditionally required; [ ] = Brackets (ie [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; MP = manufacturing-use product; EP = End-Use Product; (asterisk) identifies those data requirements that end-use applicants (i.e. "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source; TGAI = Technical grade of the active ingredient; PAI = "Pure" active ingredient; PAIRA = "Pure" active ingredient, radio-labeled; Choice = choice of several test substances, depending on studies required.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if test material is a gas or highly volatile.

(2) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as toxicity category I on the basis of potential eye and dermal irritation effects.

(3) Required unless repeated dermal exposure does not occur under conditions of use.

(4) Not required unless test material is an organophosphate, or a metabolite or degradation product thereof which causes acetyl cholinesterase depression or is structurally related to a substance that causes delayed neurotoxicity.

(5) Required if use involves purposeful dermal application to, or prolonged exposure of, human skin.

(6) Required if use may result in repeated inhalation exposure at a concentration likely to be toxic. A test with duration of 21 days is required if pesticide is used on tobacco.

(7) Required if acute delayed neurotoxicity test showed neuropathy or neurotoxicity or if closely related structural to a compound which can induce these effects.

(8) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.

(9)(i) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies (i.e., a combined study) can be conducted.

(ii) Minimum acceptable test durations for chronic feeding and oncogenicity studies are as follows:

(A) Chronic rodent feeding study (food use pesticides)—24 months.

(B) Chronic rodent feeding study (non-food pesticides)—12 months is usually sufficient.

(C) Chronic nonrodent (i.e., dog) feeding study—12 months.

(D) Mouse oncogenicity study—18 months.

(E) Rat oncogenicity study—24 months.

(10) Required to support products intended for food uses and to support products intended for non-food uses if significant exposure of human females of child bearing age may reasonably be expected.

(11) Required to support products intended for food uses and to support products intended for non-food uses if use of the product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example: pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).

(12) Required on a case by case basis.

(13) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a one year (or longer) interim report on a chronic feed study is required to support a temporary tolerance.

(14) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a first generation (or longer) interim report on a multigeneration reproduction study is required to support a temporary tolerance.

(15) A teratology study in one species is required to support a temporary tolerance.

(16) Required if the product consists of, or under conditions of use will result in, an inhalable material (e.g., gas volatile substances, or aerosol/particulate).

(17) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via the oral route.

(ii) Expected human exposure is over a limited portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, products requiring a temporary tolerance to support an experimental use permit or emergency exemption).

(18) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via skin contact.

(ii) Expected human skin contact is not purposeful, and such exposure is of limited frequence and duration (for example, such exposure could result from use of certain disinfectant, liquid fumigant or agricultural or home/garden pesticide products, and other circumstances where the Agency determines that more than acute dermal exposure is involved).

(iii) Data from a subchronic 90-day dermal toxicity study are not required.

(19) Required if pesticide use will involve purposeful application to the human skin or will result in comparable human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:

(i) Data from a subchronic oral study are not required.

(ii) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.

(20) Required if either of the following criteria are met:

(i) Use of the pesticide product is likely to result in repeated human exposure to the product, over a significant portion of the human life-span (for example, products intended for use in and around residences, swimming pools, and enclosed working spaces or their immediate vicinity).

(ii) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires issuance of a food additive regulation.

(21) Required if any of the following criteria are met:

(i) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:

(A) Is structurally related to a recognized carcinogen.

(B) Is a substance that cause mutagenic effect as demonstrated by *in vitro* or *in vivo* testing.

(C) Produces in subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that may lead to neoplastic change.

(ii) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.

(iii) Use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the time the exposure occurs or the duration of exposure (for example, pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).

(22)(i) The required battery of mutagenic tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in § 158.105:

(A) Gene mutations.

(B) Structural chromosomal aberrations.

(C) Other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome aberrations, direct DNA damage and repair, mammalian cells transformation, target organ/cell analysis.

(ii) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the battery of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency: test selection protocol design and results of preliminary testing.

(iii) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed bait boxes).

(23) Required if chronic feeding or oncogenicity studies are required.

(24) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

(Approved by the Office of Management and Budget under control numbers 2000-0483 and 2000-0468.)

§ 158.140 Reentry protection data requirements.

(a) *Table.* Sections 158.30 and 158.100 through 158.102 describe how to use this table to determine the reentry protection data requirements and the substance to be tested.

OMB Approval No. 2000-0468
Expiration Date 5/31/86

ATTACHMENT D

"GENERIC" DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified above, I hereby certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the active ingredient _____ under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the grounds that the product is an end-use product, as opposed to a manufacturing-use product, and it contains the active ingredient solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient in my firm's product. My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended in accordance with FIFRA Section 3(c)(2)(B).

Dated: _____

Registrant's authorized representative: _____
(Signature)

_____
(Typed)

Attachment: Completed Confidential Statement of Formula unless the following certification is completed:

"The CSF dated _____ on file with the EPA is complete, current and accurate and contains the information requested on the current CSF form No. 8570-4. The registered source(s) of _____ in my product(s) is/are _____ and the registration number(s) is/are _____ .

CONFIDENTIAL BUSINESS INFORMATION - DOES NOT CONTAIN NATIONAL SECURITY INFORMATION (E.O. 12065)

OMB No. 2000-0012

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (TS-767)
WASHINGTON, D.C. 20460

CONFIDENTIAL STATEMENT OF FORMULA

☐ BASIC FORMULATION
☐ ALTERNATE FORMULATION

A

See instructions on back of last page.

1. NAME AND ADDRESS OF APPLICANT/REGISTRANT (Include ZIP Code)	2. PAGE OF	3. REGISTRATION NUMBER/FILE SYMBOL	4. PRODUCT MANAGER
	5. PRODUCT NAME		
6. NAME AND ADDRESS OF PRODUCER (Include ZIP Code)	7. WEIGHT/GALLON DENSITY	8. pH	9. FLASH POINT/FLAME EXTENSION
	10. COUNTRY WHERE FORMULATED		

COMMERCIAL COMPONENT (List each as actually introduced into this formulation. Give Trade Name (if any). Name of Supplier, and EPA Registration Number if applicable.)	12. SUPPLIER	13. EPA REG. NO.	14. WEIGHT OF EACH COMPONENT*	15. PERCENT BY WEIGHT	16. PURPOSE IN FORMULATION
*If liquid measure, give specific gravity or pounds per gallon.	17. TOTAL WEIGHT OF BATCH			100.00%	

18. TYPED NAME OF APPROVING OFFICIAL	19. TITLE	20. TELEPHONE NO. (Include area code)	21. DATE

23

EPA Form 8570-4 (Rev. 10-81) PREVIOUS EDITION IS OBSOLETE.

ORIGINAL COPY TO EPA
APPLICANT RETAINS SECOND COPY

INSTRUCTIONS

PLEASE READ CAREFULLY BEFORE COMPLETING THIS FORM

The complete chemical composition of each pesticide must be known so it can be evaluated for registration under the Federal Insecticide, Fungicide, and Rodenticide Act. This information is also necessary to determine the status of ingredients, both active and inert, under the Pesticide Chemicals Amendment to the Federal Food, Drug and Cosmetic Act.

This form is designed for reporting the ingredients used in the formulation of a pesticide. It must be completed and submitted with each Application for New Registration of a Pesticide and Application for Amended Registration of a Pesticide if such revision involves a formula change.

BLOCK A - Check the appropriate action for which you are submitting this form.

1. Name and Address of Applicant/Registrant - Enter the name and mailing address of your firm or authorized agent.

2. Number all pages consecutivly. Enter on each page, the total number of pages being submitted. If more than one page is required, number them "1 of 2", "1 of 3", etc.

3. Registration No. File Symbol - Enter the EPA Registration No. or File Symbol, if known, for this product.

4. Product Manager - Enter the name of the Product Manager assigned to this product, if known.

5. Product Name - Specify the complete product name of this pesticide as it will appear on the label. This name must be the same as appears on the Application form.

6. Name and Address of Producer - Specify the name of the producer and address of the site where this product will be produced.

7. Weight/Gallon Density - For a liquid product specify pounds per gallon. For a powder or granular product, enter bulk density *(as used)*.

8. pH - Enter the pH of aqueous formulations. If not applicable, enter "N/A".

9. Flash Point/Flame Extension - Specify the flash point as determined by the Regulations for products known or suspected to burn. State the results of the flame extension test for pressurized products, including positive flashbacks.

10. Country where Formulated - If other than U.S.A., specify the country in which this product is formulated.

11. Commercial Components - List each as actually introduced into the formulation. No alternate components are acceptable if a change in the ingredient statement will result. Minor variations in the formula may be permitted, provided the ingredient statement remains the same; but a seperate EPA Form 8570-4, Confidential Statement of Formula will be required in each case.

12. Supplier - List the name of the supplier of each component. If one or more components will be obtained from more than one source, specify all the alternate sources.

13. EPA Reg. No. - Specify EPA Registration Number, if any, for each component.

14. Weight of Each Component - Specify the quantity of each component as actually introduced into the formulation. Any units *(e.g. pounds, grams, gallons, liters)* should be expressed as used in formulation. If the quantity is a liquid measure, enter the specific gravity or the pounds per gallon of the component.

15. Percent by Weight - Specify the weight percent of each component in your product. CHECK YOUR CALCULATIONS: Note the weight percent in many cases will not agree with that shown in the ingredient statement where the weight percent of the pure active ingredient(s) only must be declared.

16. Purpose in Formulation - Specify the purpose of each ingredient both active and inert. *(For example: disinfectant, herbicide, synergist, surfactant, defoamer, sequestrant, etc).*

17. Total Weight of Batch - Specify the total weight of batch *(column #14)*.

18 21. Complete these items for identification of an individual to be contacted if necessary.

42