

Fax-On-Demand
Telephone: (202)401-0527
Item: 6106

PESTICIDE REGISTRATION (PR) NOTICE 98-1

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Self-Certification Of Product Chemistry Data

The Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA) announces a "self-certification" program for certain product chemistry data of manufacturing-use products (MP) and end-use products (EP) produced by a non-integrated formulation system. This program is voluntary and is intended to simplify and accelerate the processing of applications for registration and reregistration while maintaining protection of public health and the environment.

Under the self-certification program, applicants will submit a one-page summary of the product's physical/chemical properties, but will no longer be required to submit the study upon which the summary is based. The registrants must, however, retain in their possession studies which are conducted in substantial conformity with Agency guidelines and which must be submitted to EPA upon request.

No registrant is required to use the self-certification program. Applications for new registration and reregistration may continue to be submitted under normal review procedures.

This program will be effective for applications received immediately after publication of this Notice.

I. INTRODUCTION

Product chemistry data requirements for registration and reregistration of pesticide chemicals include product identity/composition, manufacturing/formulation processes, analysis and certification of product ingredients, and physical/chemical properties. These requirements are outlined in 40 CFR 158.150 to §158.190 for chemical pesticides (conventional), §158.690 for biochemical pesticides, and §158.740 for microbial pesticides. Detailed guidance on how to conduct these studies is outlined in OPPTS Test Guidelines Series 830 - Product Properties (EPA publication 712-C-96-310, 8/96); OPPTS Test Guidelines, Series 880 - Biochemical Test Guidelines; and OPPTS Test Guidelines, Series 885 - Microbial Pesticides Test Guidelines, Overview of Microbial Pest Control Agents. It should be noted that OPPTS Test Guidelines, Series 830 supersedes the Pesticide Assessment Guidelines, Subdivision-D, Product Chemistry for chemical pesticides; and OPPTS Test Guidelines Series 880 and 885 for Biochemical and

Microbial Pesticides, respectively, supersedes the Pesticide Testing Guidelines, Subdivision M for Microbial And Biochemical Pest Control Agents. In addition to a review of data, product chemistry review entails evaluation of the label and the Confidential Statement of Formula (CSF). The requirements pertaining to the physical/chemical properties for chemical pesticides are outlined in a table of 40 CFR 158.190.

II. PRODUCTS ELIGIBLE FOR SELF-CERTIFICATION

This PR Notice applies to applications for registration or reregistration of manufacturing-use and end-use products of chemical, biochemical and microbial pesticide products produced by a "non-integrated formulation system." To be eligible for self-certification a product must be formulated from registered source(s).

This notice applies only to the self-certification of the information in support of the physical/chemical properties for these products (applicable studies in Series 830-6302 to 830-7950). Other requirements pertaining to product chemistry are not within the scope of this policy (e.g., 40 CFR 158.150 to 158.180, applicable studies in Guideline Series 830-1550 to 830-1900, Good Laboratory Practice Standards (GLP) certification, confidentiality statement, labels and CSFs).

This Notice does not supersede any regulations. Consistent with PR Notice 92-5, applicants need not submit summaries of color and odor of certain end-use products and, except as specified in PR Notice 92-5, the Agency will not request data on these properties. Applicants are advised, however, to summarize the results of color and odor for all MPs and the storage stability study for all MPs and EPs and, when requested, submit supporting data. Since PR Notice 92-5 calls for generating the storage stability data for certain EPs to be submitted upon request, a summary of this data should be included on the form.

III. PROCEDURE FOR SELF-CERTIFICATION

Applicants for registration or reregistration of pesticide products participating in this program will submit together with other requirements not within the scope of this policy, conforming with PR Notice 86-5: (a) a title page; (b) a confidentiality statement consistent with 40 CFR Part 158.33; (c) a GLP statement; (d) a self-certification statement that the physical/chemical properties data was generated in substantial conformity with OPPTS Test Guidelines Series 830, Product Properties, applicable to the subject product, and in effect at the time of submission (EPA Form 8570-37); and (e) a summary of applicable studies in Series 830-6302 to 830-7950 pertaining to the physical/chemical properties on a one-page form (EPA Form 8570-36, page 1 of Attachment 1).

A blank copy of EPA form 8570-36 (Summary of the Physical/Chemical Properties) and instructions are provided as Attachment 1 to this Notice (the form may be copied for use). Attachment 2 (EPA Form 8570-37) is a self-certification statement that must be completed and signed by the authorized representative for a pesticide applicant. Attachment 3 (EPA Form 8570-38) is a sample filled-in form showing how data summaries of some properties can be presented.

Electronic copies of EPA Form 8570-36 (Attachment 1) are available upon request. The form is expandable to allow reporting the requirements for registration/reregistration on separate sheets identified by product's name and Reg. No./File Symbol No. The instructions can be copied on the back of the form to save paper. Applicable data requirements in Series 830-6302 to 830-7950 pertaining to the physical/chemical properties, whether generated by the applicant, shared or referenced data, must be cited on the form according to the instructions.

The GLP requirements of 40 CFR Part 160 and OPPTS Test Guidelines Series 830, Product Properties (EPA publication 712-C-96-310, 8/96) apply to the data covered by this Notice. Applicants wishing to participate in this program must submit a GLP compliance statement in accordance with 40 CFR Part 160.12(a) which indicates that the data covered by this Notice were conducted in compliance with all applicable GLP requirements set forth in 40 CFR 160. Note that under Sections 160.135(b), with the exception of the storage stability study, certain GLP provisions are not applicable to studies covered by this Notice.

IV. EPA REQUESTS FOR SUPPORTING DATA

EPA may at its discretion request that applicants and registrants submit the supporting data to ascertain that the studies were conducted in compliance with OPPTS Test Guidelines Series 830, Product Properties, and are consistent with the summary and GLP certification. If a registrant fails to respond adequately to such a request, the Agency will treat the application as follows:

A. Applications for registration

Normally, EPA will not request an applicant to submit the underlying studies, but will rely on the data summary to evaluate the registration or reregistration. However, if the Agency requests the studies, the applicant must submit the underlying product chemistry data within thirty (30) days of registrants receipt of the Agency's request or within another specified time period agreed to by the Agency. If the applicant fails to meet the deadline, the Agency will treat the application as incomplete pursuant to 40 CFR 152.105.

B. Data Required Under Data Call-In Notice (DCI)

Normally, registrants required to satisfy the physical/chemical properties data as part of a Data Call-In Notice (DCI) in reregistration may satisfy the requirements by submitting the summary form and other information set forth in this Notice (Part II above) in lieu of submitting the supporting data itself. As noted above, however, the Agency may request submission of the data and allow thirty (30) days (or within another specified time period agreed to by the Agency) from registrant's receipt of the Agency's notification for submission. The Agency will treat the failure to submit such supporting data upon request as a failure to comply with the DCI and may suspend the registration under FIFRA Sec. 3(c)(2)(B).

C. Data Requested as Part of an Audit

EPA may request the submission of the underlying data as part of an audit to determine compliance with EPA regulations and ensure that the supporting data are consistent with the summary and GLP/self-certification statements submitted by the applicant or registrant. If a registrant fails to submit such data upon request, EPA may suspend the registration as provided by the registrant's certification.

V. REQUEST FOR RESPONSE

If, after review of the data summary under the self-certification program, or selective review of the supporting data, EPA determines that:

The physical/chemical properties values are not adequately supported by the test data;

One or more of the reported product properties appears to be in error; or

The GLP certification is incorrect; then

EPA will request the applicant to submit to the Agency, within thirty (30) days (or within another specified time period agreed to by the Agency) of a registrant's receipt of the Agency's request, a satisfactory response to the notification. EPA might request that the applicant:

Submit additional information if the submitted summaries are inadequate;

Explain why deviations from the guidelines were considered necessary;

Provide an explanation as to why the Agency should not pursue enforcement action; or

Provide an explanation as to why the Agency should not suspend the applicant's registration pursuant to the registrant's certification or take other regulatory action.

VI. POSSIBLE TERMINATION OF THE SELF-CERTIFICATION PROGRAM

EPA may terminate the self-certification program at any time and will issue another PR Notice to registrants if it does so. Factors that could lead the Agency to terminate self-certification include a high incidence of errors in the reported summary of the physical/chemical properties, non-participation by applicants, or the program's failure to fulfill the needs of the Office of Pesticide Programs. For example, if EPA finds that more time is required to assess the reported physical/chemical properties than in reviewing the full data requirements, it would likely terminate the self-certification program.

VII. PAPERWORK REDUCTION ACT NOTICE

The annual public burden for the collection of information associated with the self-certification opportunity described in this PR-Notice has been approved by the Office of Management and Budget (OMB) under OMB Control No. 2070-0060 (EPA ICR # 277.10), OMB Control No. 2070-0107 (EPA ICR # 1504.03), and OMB Control No. 2070-0057 (EPA ICR # 922.05), and is estimated at 1.25 hours per response. The revised total burden to accommodate the voluntary electronic submission of CRP data as described in this PR-Notice is estimated to be 1.25 hours per response. The Agency has therefore adjusted the burden hours under OMB Control No. 2070-005 to account for the slight increase in burden associated with making this information available electronically. According to the Paperwork Reduction Act, "burden" means the total time, effort or financial resources expended by persons to generate, maintain, retain or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; to disclose and provide information, and to transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9, and appear on any related information collection instrument.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M Street, S.W., Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not submit the requested information to this address. The requested information should be submitted in accordance with the instructions in this PR Notice.

VIII. EFFECTIVE DATE

This policy will become effective for applications submitted immediately after publication of this Notice. Applications received before the effective date will not be eligible for self-certification because of the burden associated with submitting and processing new requests for a change-over to self-certification.

IX. ADDITIONAL INFORMATION

If you have questions on the self-certification program, or want a copy of this Notice, please contact:

Dr. Sami Malak
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
401 M St, S. W.
Washington, D. C. 20460

Telephone: (703) 308-9365 FAX: (703) 308-9382
e-mail: malak.sami@epamail.epa.gov

Stephen L. Johnson, Acting Director
Office of Pesticide Programs

Attachments:

1. Summary Table, EPA Form 8570-36, plus Instructions (one page each).
2. A Self-Certification Statement, EPA Form 8570-37 (one page).
3. Filled-In Summary Table, EPA Form 8570-38 (one page).



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1 hour per response for registration activities and 1 hour per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME:		2. Reg. No.
3. COMPANY NAME:		4. SUBMISSION DATE:
5. FIRST SUBMISSION [] 6. RESUBMISSION []	7. PESTICIDE TYPE:	10. REGISTRATION []
8. FORMULATED MANUFACTURING-USE PRODUCT [] or 9. END-USE PRODUCT []		11. REREGISTRATION []
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN):		12. REREG CASE #
14. GUIDELINE REFERENCE NO.(GRN)/TITLE	15. VALUE or QUALITATIVE DESCRIPTION/METHOD(S) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)

-6302	Color		
-6303	Physical State		
-6304	Odor		
-6314	Oxidation/Reduction: Chemical Incompatibility		
-6315	Flammability/Flame Extension		
-6316	Explosibility		
-6317	Storage Stability		
-6319	Miscibility		
-6320	Corrosion Characteristics		
-6321	Dielectric Breakdown Voltage		
-7000	pH		
-7100	Viscosity		
-7300	Density/Relative Density/ Bulk Density		

INSTRUCTIONS ON HOW TO COMPLETE THE SUMMARY FORM (PR NOTICE 98-1)

1, 3 to 6 & 8 to 13: Self-explanatory.

2: Cite Registration Number or File Symbol Number. Leave blank if unknown or cite company number followed by a hyphen and XXX.

7: State whether your product is an insecticide, herbicide, fungicide, rodenticide, plant growth regulator, etc.

14: OPPTS Test Guidelines, Series 830, Product Properties (EPA publication 712-C-96-310,8/96) supersedes the Pesticide Assessment Guidelines, Subdivision-D, Product Chemistry, Series 60 to 64, and serves as one guideline for national and international product chemistry data requirements for chemical pesticides. Consistent with the certification statement, applicants must conduct the studies in substantial conformity with the detailed procedures described in OPPTS Test Guidelines. Published procedures or modifications may be used but must be referenced. If the applicant/registrant is fulfilling product chemistry requirements for a biochemical or microbial pesticides, cite the requirements opposite the corresponding GRNs listed on the form for chemical pesticides.

15: Indicate the experimental value, its average deviation and, where applicable, the method used, e.g., GC, HPLC, DTA/DSC (differential thermal analysis/scanning calorimetry). Provide qualitative descriptions, where applicable, and references such as ASTM, CIPAC, OECD, Federal Register, CFR, CRC Publication, Official Journal of the European Communities, EPA's Guidelines, etc. Examples on how to report some of these properties are shown on Attachment 3. Non-applicable studies can be indicated by using the term "N/A or Not-Applicable" then citing a regulatory and/or scientific reason as per the footnotes to the Table in 40 CFR 158.190. Studies in progress can be indicated as such "I/P or In Progress." Values or qualitative description of referenced or shared studies should also be indicated on the Form. All boxes in the form must be completed with data summaries and appropriate terms if not applicable or in progress. Resubmissions can be completed using a new form citing the applicants's response to the specific data gap or deficiencies and filling the remaining boxes with "N/A or Not-Applicable" if previously submitted and found adequate or "Upgraded" if a submitted study was rejected and needed upgrading, then cite the date of preceding data submissions followed by a summary of the upgraded information. The Form is expandable to allow reporting the requirements for registration/reregistration on separate sheets identified by product's name and Reg. No./File Symbol or Company No. Please note that abbreviations may be used if explained by identifying the corresponding full terms as footnotes to the Form.

16: Indicate company Report number if the study was generated and retained by the applicant or MRID number (Master Record Identification Number) if the study was previously submitted and assigned a number by the EPA. Company report number should not exceed eighteen (18) characters. It will be used by the Agency to recall certain studies if needed. When received by the Agency, properly formatted data will be assigned MRID number(s).

Specific Instructions by Guideline Reference Number (GRN)

GRNs 830-6319, -6321, -7000, -7100 & -7300 should be conducted in compliance with OPPTS Test Guidelines Series 830 Product Properties, or reported at 25°C unless otherwise noted.

GRN 830-6302, -6303 & -6317: Report qualitative description where applicable as per PR Notice 92-5.

GRN's 830-6315, -7000 & -7300: Reported values on the form should be consistent with those given on the Confidential Statement of Formula (CSF).

GRN 830-6303: Provide a brief description, e.g., solid, granular, liquid, powder, aqueous solution, emulsion, volatile liquid, gas, etc.

GRN 830-6314: Not applicable if the product does not contain an oxidizing or reducing agent or functional group of significant reactivity. This requirement includes those substances which the product is likely to contact including the storage container and dispensers during handling and use, e.g., iron, aluminum.

GRN 830-6315 For organic liquids, provide flash point in degrees Celsius (with Fahrenheit in parentheses). For aerosols provide flame extension and/or flash back if applicable to the nearest centimeters (with inches in parentheses). For non-combustible liquids and solids state "Non-Applicable."

GRN 830-6316: Indicate method of determination and cite references, e.g., differential thermal analysis/scanning calorimetry (DTA/DSC), (sharp exotherm at 60 degrees Celsius), by shock or impact explosibility, hammer test or by structural analog, contains several nitro groups as in picric acid.

GRN 830-6317: Should be conducted for a minimum of one year under ambient warehouse conditions using commercial containers. Report the type of containers used and any changes in product composition at intervals of three months to the end of the test period relative to that at the beginning of testing. Any physical changes at the end of the test period must also be reported. Data on the stability study for technical grade of active ingredients (GRN 830-6313) will not satisfy the requirements for the storage stability (GRN 830-6317) for qualifying products. An interim 30 days storage stability study can be included with the first submission requesting a conditional registration pending compliance with all the requirements.

GRN 830-6320: May be conducted simultaneously with GRN 830-6317. Indicate changes in the commercial packaging containers (fluorinated high density polyethylene, plastic film, polyethylene liners, steel, tin, or paper) over a minimum of one year in storage under warehouse conditions.

GRN 830-7100: Flow curves for non-Newtonian fluids on viscosity can be appended to the form.

GRN 830-7300: For solids or powders, provide the bulk density in units, e.g., g/cc or lb/ft³ whichever is preferred. For liquids, provide the density in grams/ml or lbs/gal.

Attach-1



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401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**SELF-CERTIFICATION STATEMENT FOR THE
PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)**

Product Name:

Reg. No./File Symbol No.
(if known) or Company No.

SELF-CERTIFICATION STATEMENT:

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): _____ and that the values of the properties reported are reliable.

I further certify that such data was generated in substantial conformity with OPPTS Test Guidelines Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name:

Title:

Telephone No.

Applicant's Signature:

Date:

SAMPLE FORM

Form Approved OMB No. 2070-0060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1 hour per response for RD and 1 hour per response for SRRD activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Mangement Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

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3. COMPANY NAME		4. SUBMISSION DATE:
4. First SUBMISSION [] 5. RESUBMISSION []	7. PESTICIDE TYPE:	10. REGISTRATION []
8. FORMULATED MANUFACTURING-USE PRODUCT [] OR 9. END-USE PRODUCT []		11. REREGISTRATION []
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN):		12. REREG CASE No.:
14. GUIDELINE REFERENCE NO.(GRN)/TITLE	15. VALUE OR QUALITATIVE DESCRIPTION/METHOD(S) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)

-6302	Color	White.	PC0297-X1
-6303	Physical State	Liquid.	PC0297-X2
-6304	Odor	Odorless.	PC0297-X3
-6314	Oxidation/Reduction: Chemical Incompatibility	No reaction was observed when the test substance was mixed, for one hour at @ 20°C, with zinc or iron powder: Ref. 44FR16267, 3/16/1979.	PC0397-X1
-6315	Flammability/Flame Extension	60°C, using MRI SOP No. PCA-515C, Flash Point - Pensky Martens Closed Tester.	PC0397-X2
-6316	Exploability	Not explosive based on structure and DSC test to 200°C.	PC0397-X3
-6317	Storage Stability	No change in concentration of the active ingredients when stored for one year under ambient warehouse conditions in commercial packaging material composed of fluorinated High Density Polyethylene. Duplicate analysis of three samples, using the enforcement method, gave >99% activity.	432167-03
-6319	Miscibility	Completely miscible with petroleum solvents.	PC0497-X1
-6320	Corrosion Characteristics	No evidence of corrosion of the container was observed when the test substance was stored for one year under ambient warehouse conditions in commercial packaging material composed of fluorinated High Density Polyethylene: Ref. MRI SOP #LS-520.	432167-03
-6321	Dielectric Breakdown Voltage	Not applicable. Not to be used around electrical equipment.	-----
-7000	pH	5.9 at 25°C in 1% solution using a digital pH meter.	PC0497-X2
-7100	Viscosity	45 centipoise at @ 25°C using a Brookfield Digital Viscometer: Ref. ALP-013-0.	PC0497-X3
-7300	Density/Relative Density/ Bulk Density	1.965. @ 25°C using a specific gravity pycnometer: Ref. CIPAC Handbook, Vol 1, "MT-3-Specific Gravity and Density, 1970."	PC0497-X4