Index of this Electronic Publication:

* see guidance below

Electronic copies of EPA forms:

8570-34 ("Certification with Respect to Citation of Data")
8570-35 ("Data Matrix")

Important: In electronic format there are two different copies of form 8570-35 ("Data Matrix"). The "Public File Copy" has the columns for Guideline Reference Number, Guideline Study Name and MRID Number blacked out. This is equivalent to the second sheet in the chemical transfer, paper, version where these columns are also blacked out so that information is not transferred from the top sheet. The "Agency Internal Use Copy" is the same as the top sheet in the paper version where the columns for Guideline Reference Number, Guideline Study Name and MRID Number are legible. If you are using the electronically available version of this form, *you must submit both the "Public File Copy" and the "Agency Internal Use Copy" to the Agency.*

Only paper copies of the forms will be accepted at this time. *Do not send electronic copies of these forms to the Office of Pesticide Programs.*

Fax-On-Demand
Telephone: (202) 401-0527
Item: 6112

6/12/1998

PESTICIDE REGISTRATION (PR) NOTICE 98-5

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

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

SUBJECT: New forms for the Certification with Respect to Citation of Data

I. INTRODUCTION

The Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA) announces new forms for citation of data to support the registration or reregistration of pesticide products. EPA Forms 8570-34 ("Certification with Respect to Citation of Data") and 8570-35 ("Data Matrix").

Form 8570-34 replaces Forms 8570-29 and 8570-31 and Form 8570-35 replaces Form 8570-20 and the "Blue Book Sample Matrix Format." *As of the date of this notice the old forms may no longer be used*. The new forms will streamline data compensation for both registration and reregistration of pesticide products by merging three forms into two and by reducing the paperwork burden for both EPA and the pesticide industry. The same forms will be used for the registration, reregistration and special review[1] of pesticides.

II. BACKGROUND INFORMATION

The Environmental Protection Agency (EPA, or the Agency) is responsible under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registering pesticide products on the basis of scientific data or other information adequate to show that, among other things, the products will not pose unreasonable adverse effects on the environment. After registration, under section 3(c)(2)(B) of FIFRA, EPA may require pesticide registrants to generate and submit data to the Agency where such data is needed to assess whether certain pesticides should continue to be registered.

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[1] when responding to data call-ins issued under section 3(c)(2)(B) of FIFRA

An individual or entity wanting to obtain or maintain a registration for a pesticide product must submit an application package consisting of information relating to the identity and composition of the product, and supporting data or a citation to supporting data that have previously been submitted to the Agency. In the latter case, the applicant generally must also certify that an offer of compensation has been made to the original data submitter or that the submitter has granted permission to cite data. Applicants make this certification by submitting a "Certification with Respect to Citation of Data" form (Now Form 8570-34, which replaces Forms 8570-29 and -31).

The consequence of using another company's data to support a pesticide registration without an offer of compensation is possible cancellation of the pesticide registration. FIFRA places an obligation on the Agency to ensure that the original data submitter is offered compensation for the use of data. The specifics as to the amount and terms of compensation are not within the Agency's purview. Rather, the Federal Mediation and Conciliation Service will appoint an arbitrator to resolve these specifics upon the request of either party.

In the mid-1990s, the pesticide industry formed a "Data Compensation Task Force" consisting of pesticide manufacturers, formulators, and distributors. Collectively, the group represents both original data submitters and those that use another's data to support registration. The Task Force was formed to develop a mechanism for the pesticide industry to better protect its data rights by, among other things, making it easier for industry to self-police the FIFRA data compensation scheme.

The Task Force provided input to EPA for improving the existing data citation and compensation forms used by the Agency to track compliance with the requirements of FIFRA. The Agency agreed that improvements could be made and has therefore developed a new EPA Form 8570-34 ("Certification With Respect to Citation of Data") and EPA Form 8570-35 ("Data Matrix"). These forms will be used for registration, reregistration and special review purposes. Form 8570-34 and the "Public File Copy" of Form 8570-35 will be placed in a publicly available file once a pesticide is registered. This file will provide data submitters with faster, easier access to these documents than can be obtained through the Freedom of Information Act.

III. OVERVIEW OF CHANGES IN NEW FORMS

EPA Forms 8570-34 ("Certification with Respect to Citation of Data") and 8570-35 ("Data Matrix") supplement and are integral to one another. These forms have been modified to be user-friendly and add additional information for tracking data citation. A copy of these new forms is attached to this notice. For each product, both forms will be available for public inspection once it is registered.

a. EPA Form 8570-34, Certification with Respect to Citation of Data:

Form 8570-34 replaces Forms 8570-29 and 8570-31. Pesticide registrants must use this form to indicate how they will meet their data submission/data citation obligations under FIFRA. When a registrant refers to another company's data, it must certify that an offer of compensation has been made to the original data submitter or that it has the original data submitter's permission to cite the data and it must now indicate that it has evidence on file that an offer has been made or that permission has been granted. It should be noted that Form 8570-34 does not replace Form 8570-32, Certification of Offer to Cost Share in the Development of Data.

This form has been modified to add four items. First, the names of the active ingredients and/or representative test compounds are required at the top of the form. Second the use pattern for the product is required. Third, the telephone number for the applicant is required. And fourth, the applicant must indicate whether it is using the cite-all method of support or whether it is using the selective method of support. Also the form contains a brief description of the possible penalties for improperly citing data. The form remains one page.

b. EPA Form 8570-35, Data Matrix

The second revised form (8570-35), the data matrix, replaces the existing form (8750-20) and the "Blue Book Sample Matrix Format." The data matrix must be used under the selective method. The matrix should also be used under the cite-all method to indicate the companies to whom offers of compensation were made.

The revised data matrix form provides more clarity regarding the information cited by the applicant. To ensure consistency, these forms would be used for reregistration as well as registration and special review. The new form has completely revised instructions. The instructions are designed to be user friendly, increase accuracy, and reduce the time spent completing the form.

There are two different copies of Form 8570-35. The "Public File Copy" and the "Agency Internal Use Copy." The Agency Internal Use Copy is normally retained for Agency use but is available by request under the Freedom Of Information Act. The Public File Copy will not contain the guideline reference number, the guideline study name, and the MRID number but will indicate the submitter and status of the data. This version of the data matrix will be available for public inspection along with Form 8570-34, once a product is registered.

In the paper, chemical transfer, version of Form 8570-35, the second sheet is the "Public File Copy." It has the columns for Guideline Reference Number, Guideline Study Name and MRID Number blacked out so that this information is not transferred from the top (Agency Internal Use Copy) sheet. The "Agency Internal Use Copy" or

top sheet in the paper version and has the columns for Guideline Reference Number, Guideline Study Name and MRID Number legible.

Important: If you are using the electronically available version of this form, *you must submit both the "Public File Copy" and the "Agency Internal Use Copy."* The forms must be submitted in paper. The Agency cannot accept electronic submission.

The new Data Matrix, EPA Form 8570-35, provides a more detailed explanation of how to fill out the form than the "Blue Book Sample Matrix Format" and Form 8570-20. Registrants are required to date and sign the form including their title. The form will eliminate the return receipt to the registrant which reduces the Agency's burden. The box requesting to be on the DSL (Data Submitters List) is not on the new form. Effective the date of this notice, registrants submitting data will automatically be added to the DSL. If a registrant does not want to be added to the DSL they must notify the Agency in writing at:

Office of Pesticide Programs 7504C [DSL]
U.S. Environmental Protection Agency
401 M St, S. W.
Washington, D. C. 20460

It is the registrant's responsibility to verify that the information on the DSL is correct. Corrections to DSL should be sent in writing to the above address.

The new Data Matrix will provide a clear indication of the information required, and it will avoid confusion over when the "Blue Book Sample Matrix Format" should be used as opposed to Form 8570-20. Further, original data submitters will find it easier to ascertain if their data has been cited and whether or not they were purportedly sent offers of compensation. Even though registrants will have more clarity using the new Data Matrix, the amount of time needed to complete the form is the same as Form 8570-20 or the "Blue Book Sample Matrix format."

IV. EFFECTIVE DATE

Forms 8570-34 and 8570-35 should now be used for all registration, reregistration and special review activities. Old Forms 8570-29, 8570-31, 8570-20 and "Blue Book Sample Matrix Format" will not be accepted effective upon publication of this notice.

V. ADDITIONAL INFORMATION

Electronic copies of Forms 8570-34 and 8570-35 ("Public File Copy" and "Agency Internal Use Copy.") are available on the Internet at **http://www.epa.gov/ opppmsd1/PR_Notices**. The forms are attached at the end of the PR Notice.

Paper copies of Forms 8570-34 and 8570-35: Please get these forms from our Internet site if you can. If you do not have Internet access, paper copies can be requested from:

Registration Division
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
401 M St, S. W.
Washington, D. C. 20460
Phone: (703) 305-6549

If you have questions about the new data compensation forms, please contact your Agency representative in the appropriate regulatory division or contact:

Alan Dixon
Registration Division (7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M St, S. W.
Washington, D. C. 20460
Telephone: (703) 305-7237
FAX: (703) 305-6920
e-mail: dixon.alan@epamail.epa.gov

For registered products, copies of submitted data compensation Forms 8570-34 and 8570-35 (Public File Copy only) are available for public inspection at:

U.S. Environmental Protection Agency
Office of Pesticide Programs
Public Regulatory Docket
Crystal Mall II Building
1921 Jefferson Davis Highway - Room 119
Arlington, Virginia 22202
(703) 305-5805

/s/
James J. Jones, Director
Registration Division

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 1.25 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.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title

Form Approved OMB No. 2070-0060

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

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DATA MATRIX

Date	EPA Reg No./File Symbol	Page of
Applicant's/Registrant's Name & Address	Product	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

Signature	Name and Title	Date

Form Approved OMB No. 2070-0060

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

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DATA MATRIX

Date	EPA Reg No./File Symbol	Page of
Applicant's/Registrant's Name & Address	Product	
Ingredient		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title	Date

INSTRUCTIONS FOR DATA MATRIX

INSTRUCTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

Ingredient: Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

OWN:	I am the Original Data Submitter for this study.
EXC:	I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.
PER:	I have obtained the permission of the Original Data Submitter to use this study in support of this application.
OLD:	The study was submitted more than 15 years ago and all periods of compensation have expired.
PL:	The study is in the public literature.
PAY:	I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).
GAP:	This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.
FOR:	I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.
Note:	If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.