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GUIDELINES FOR REGISTERING PESTICIDES

IN THE

UNITED STATES

(I.) General Procedures and
(II.) General Labeling Requirements

Second Preliminary Edition
August 1972

Pesticides Regulation Division
Office of Pesticides Programs
Environmental Protection Agency
Washington, D.C. 20250

GUIDELINES FOR REGISTERING PESTICIDES

INTRODUCTION

Pesticides are regulated in the United States to insure that quality products are available to the public, and that when properly used, these products will provide consumers with effective pest control without hazard to health or significant adverse effects upon the environment.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that economic poisons (pesticides) be properly labeled and registered prior to interstate shipment. The FIFRA is administered by the Environmental Protection Agency's Pesticides Regulation Division, which registers pesticide products.

The Act and the regulations require that products must not present an unacceptable risk to man or the environment, and must be useful when used in accordance with the directions for use and other labeling. The determinations concerning safety and usefulness must be made carefully by experienced personnel, and must be based upon reliable research results. The responsibility for supplying this information rests with the applicant. If determinations of safety and usefulness can be made on the basis of generally available data (i.e., results of previous tests with the same or similar formulations which are generally available), it will not be necessary to repeat such testing. "Established patterns of use," such as those published in the Summaries or Compendiums of Registered Uses, or the Annotated Index, will usually be accepted on the basis of generally available data. This, however, will not override scientific judgment as to the adequacy or applicability of existing data to a proposed product.

Purpose

These guidelines are intended to instruct applicants in a general way on the requirements for registration, while retaining flexibility for application of sound judgment in individual cases.

GUIDELINES FOR REGISTERING PESTICIDES

The guidelines set forth procedural steps to be taken by applicants and by the Division and should assist in proper preparation and processing of applications for registration. They are intended to supplement the Act, Regulations, or Interpretations.1/

Reference should also be made to the Pesticide Chemical Regulations under the Federal Food, Drug and Cosmetic Act for procedures in petitioning for tolerances for pesticide residues in raw agricultural commodities.2/

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1/ Request from Environmental Protection Agency, Pesticides Regulation Division, 9-PR Forms, Washington, D.C. 20250.

2/ Request from Environmental Protection Agency, Pesticides Tolerances Division, Washington, D.C. 20250.

GUIDELINES FOR REGISTERING PESTICIDES

SECTION I - GENERAL PROCEDURES

Contents

Applications

Applications for registration must be submitted to the Pesticides Regulation Division, Environmental Protection Agency, Washington, D.C. 20250. Applications should be submitted as far in advance as possible prior to the desired registration date. Application should be submitted with appropriate forms as discussed below. A facsimile of each of these forms, with instructions for proper completion, is included as an addendum to this Section. Supplies of forms are available from the Division upon request.

The application must be accompanied by five legible copies of the proposed labeling, and the confidential statement of formula, and in certain cases, with supporting data. These are detailed on the following pages. Samples of proposed products are not usually required, and should not be furnished unless requested.

An applicant not residing in the United States should have an authorized firm representative residing in the United States to act in his behalf in all registration matters. The name and complete mailing address of such representative must accompany the application. Pesticide products imported into the United States must meet the same requirements as those produced and marketed domestically. They must be registered and properly labeled prior to entry.

Acknowledgement

Receipt of an application by the Division will be acknowledged by return of a carbon copy of the application form within 10 days after receipt, and the applicant will be furnished the File Symbol assigned to the application. This File Symbol (or assigned registration number, if the product is registered) must be referred to in any correspondence concerning the pending application.

Preliminary Provisional Acceptance

If the labeling submitted is acceptable, a provisional preliminary notice of acceptance will be issued to the applicant, showing the EPA Registration Number reserved for the product. This preliminary notice is subject to submission of acceptable final printed labeling, and is not to be construed as registration of the product.

Acceptance

Upon acceptance of final printed labeling bearing the assigned EPA Registration Number, a Notice of Registration will be issued to the applicant.

The registration notice designates the labeling which is permitted, and specifies any limitations imposed on the product and its labeling. All of the provisions covered by the registration notice are considered conditions of the registration. Registration becomes effective on the date the Notice of Registration is issued. Until a Notice of Registration has been issued, interstate shipment of the product is in violation of the Act.

Duration

The registration is effective for a period of five years from the time of registration of any subsequent amendment unless it is voluntarily terminated by the registrant, or suspended or cancelled for other reasons.

Rejection

If the application is rejected, the applicant will be given the opportunity to correct the labeling and resubmit it, or furnish additional information in order that review may continue. It is advisable not to proceed with printing of the labeling until the preliminary acceptance letter has been received. Unless the rejected labeling is corrected within a reasonable period of time, the applicant will be asked to withdraw the application.

Cancellation

If at any time it appears that a registered product or its labeling does not comply with the provisions of the Act, a Notice of Cancellation may be issued. This notice will state the facts involved and afford the registrant an opportunity to bring the product and its labeling into compliance with the Act. If after 30 days the registrant has not made such corrections, the registration will be cancelled under the provisions of Section 4c of the Act, unless other provisions under this section are invoked. (See also 40 CFR Part 164). These provisions allow the registrant to petition that the matter be referred to an Advisory Committee or to object and request a public hearing. Cancellation of a registration also applies to any additional product names which have been accepted under amended or supplemental registrations. During the pendancy of the administrative procedures provided for in Section 4 of the Act, the product remains registered.

Suspension

Registration may be suspended immediately at any time such action is determined to be necessary to prevent an imminent hazard to the public. In such event, the registrant will be notified immediately and will have the opportunity to refer the matter to an Advisory Committee or to an expedited public hearing. During consideration of a suspension, the product may not be shipped in interstate commerce.

Types of Registration

New Registrations

When an application for the registration of a pesticide product is submitted for the first time, the following must be filed with this Division:

1. Application for New Registration of Economic Poisons, PR Form 9-199.

2. Confidential Statement of Formula, PR Form 9-196.

3. Five copies of the proposed labeling, bearing all claims to be made for the product.

4. Three copies of applicable documents (such as data) in support of the application.

Amended Registrations

When there is a proposed change in the labeling or formula of a registered product, the registrant must submit an Application for Amended Registration, PR Form 9-198. If a change in formula is to be made, a revised Confidential Statement of Formula, PR Form 9-196, must also be submitted. An Application for amended registration is not to be construed as an approval of the change in the product or the labeling proposed in the application. Proposed amendments must be accepted for registration prior to any shipment of the product bearing the amended labeling.

Minor changes in formulation are handled as amendments of existing registrations. These may include a change in the percentage of active ingredients, or a change in inert ingredients. A major change in formulation, such as a change in the principal active ingredients, requires registration as a new product.

When a change of the product name is proposed, the registrant must file application for amended registration on PR Form 9-198 and submit five copies of the labeling showing the product name change. When an amended label draft is stamped acceptable, printed labels may be shipped without further PRD approval. Printed copies of amended labels should be sent to PRD when available.

Applications for additional product names should be submitted on PR Form 9-198. In this case, however, labeling (which must not differ in substance from the basic accepted labeling) need not be submitted. Interstate shipment under the additional brand name may not be made before the acceptance of the amendment.

If orange is registered only for further formulation do the below rules apply to the purchaser & sublabelers. What assurance do we have that the distributor will be given a registration.

Supplemental Registrations

After an economic poison has been registered, the registration can be amended to include supplemental registration for distributors. When supplemental registration is desired, the registrant must file an Application for Supplemental Registration for Distributors (PR Form 9-1). The product may not be legally shipped in interstate commerce under the distributor's label until the application has been accepted. The distributor's label must not differ in substance from the basic label accepted for the registrant, with the following exceptions:

1. The product name may differ as long as it is not misleading.

2. The name and address of the distributor must be preceded by a qualifying phrase such as, "distributed by," "sold by," or "manufactured for."

3. If the basic label bears directions for use on a number of crops or sites, the distributor's label may bear directions for use on only a part of the crops or sites, provided such directions are completed.

It is not necessary to submit copies of the distributor's labeling if copies of currently accepted printed labeling for the basic product are on file with the Division.

The distributor's label must bear the registration number assigned to the registered product. In addition to the registration number assigned to the registrant, the labeling for the distributor's product must bear the number assigned to the distributor's firm. If the distributor has a number assigned to his firm in connection with previous registration actions, this number must be used. Otherwise, a number will be assigned at the time of acceptance of the applications for supplemental registrations submitted by the registrant. The distributor's product must remain in the manufacturer's original unbroken container as long as it is in the channels of trade.

Any changes in the registration status of the manufacturer's product or its labeling apply equally to all distributor's products listed under the registration. It is the responsibility of the registrant to see that all distributors' labeling complies with the currently accepted labeling for the basic product.

Product purchased by the distributor and repackaged can not be legally shipped in interstate commerce without a separate registration. The immediate containers of products shipped from the manufacturer to the distributor for repackaging only must bear registered labeling.

Renewal Registrations

At the end of the five-year registration period, a Notice of Intent to Cancel (PR Form 9-289), will be sent to the registrant at his latest address submitted to the Division. If a registrant wishes to continue the registration in effect after the expiration of the five-year registration period, he must request renewal registration (PR Form 9-197). He must submit with this form five copies of the current labeling, including all printed or graphic matter which may accompany the product at any time. He must also submit a Confidential Statement of Formula (PR Form 9-196). Applications for renewals are subject to all current labeling and data requirements. If the product or its labeling fails to comply with current requirements, the registrant will be afforded the opportunity to make the necessary corrections.

Contents of Applications for Registration

The PR Forms required for various types of registrations have been discussed. In addition to the properly completed form, an application must be accompanied by a proposed label text. A Confidential Statement of Formula, (PR Form 9-196) must also be submitted, supporting data may also be required. These most important parts of an application are discussed below.

The term label means the written, printed, or graphic matter on or attached to the immediate container or overpacking of the pesticide product. The term labeling includes labels and also any written, printed, or graphic material accompanying the product at any time or to which reference is made on the label.

The label must bear certain essential parts: (1) the product name, (2) the registrant's name and address, (3) the net contents, (4) an ingredient statement showing the approved name(s) for the active ingredient(s), (5) the EPA Registration Number, (6) a warning or caution statement, and (7) the directions for use. Most labels also show a warranty statement or guaranty; however, there is no requirement for such statements. The Regulations and Interpretations should be consulted carefully in preparation of the proposed label text.

Five copies of the proposed labeling must be submitted with each application for new, amended, or renewal registration. The copies must be legible and identical.

If any part of the proposed labeling is in a foreign language, it must be accompanied by an accurate and complete English translation. Typewritten drafts may be submitted for review; however, finished labeling will be required before registration is issued.

Finished Labeling

Finished labeling is defined as the complete markings and text that appear on or accompany the product. Finished labeling must be legible and the graphic design must not be misleading.

Submitting Procedures

When screen printing or embossing is used to print labeling directly on the container (cans, bottles, boxes, etc.), do not submit the containers. Such labeling should be submitted after it is reproduced as follows:

(a) Screen Printing.-- Request your printer to supply finished copies of the labeling on paper for convenient filing. Copies may be obtained by taping a piece of paper on the container as it goes through the printing process.

(b) Embossing.-- Photocopy this labeling. When paste-on labeling is used, submit copies. When labeling involves large containers such as bags and boxes, submit legible photo-reduced copies indicating the fraction of actual size.

When labeling is smaller than 40 square inches, copies should be attached to a sheet of paper (8 1/2" x 11").

Statement of Formula

Applications must be supported by complete information about the formula of the proposed product (see Section 4b of the Act), if this information has not been previously supplied. A completed Confidential Statement of Formula (PR Form 9-196) must be submitted. The formula must give the chemical name, percentage by weight, and source of each ingredient, both active and inert. The statement of formula is confidential (see Section 8c of the Act).

If the required information is not available to the applicant, he must: (a) obtain the necessary information from the basic supplier, and provide this information on PR Form 9-196, or (b) request the supplier to complete this form, and to provide a statement specifically authorizing the extent of the use of such information to support separate registration for the applicant. This statement must clearly identify the products involved, including the File Symbol and/or Registration Number(s).

Ingredients, active or inert, which are part of the formula of a product to be used on food or forage crops must have a tolerance or exemption from a tolerance under the Federal Food, Drug, and Cosmetic Act. With respect to inert ingredients, consult especially Section 180.1001 of the Pesticides Regulations under this Act.

Supporting Data

When an application for new registration or an amended registration including new claims or new use patterns is made, supporting data may be required. Such data are submitted in triplicate.

Required Information

Tests should be designed and reported to evaluate each label direction for use, limitation, and caution. Pertinent details may include, but are not limited to adequate information on:

1. Year and location of the test.
2. Identity of person conducting the test.
3. Identity of the target pest.
4. Crop variety, weed, or site treated.
5. Plot size.
6. Number of applications.
7. Identity of the specific formula tested, including the name and volume of any diluent used.
8. Dosage in terms of amount, specified as formulation or actual active ingredient, per acre of crop, and when applicable, in terms of equivalent broadcast rate per acre.
9. If a crop is band treated, the placement and width of the band, and the distance between crop rows.
10. Method of application.
11. Date and stage of crop or weed growth at each time of application.
12. Soil type, including percentage of organic matter.
13. Identity of rating scale(s) used.
14. Date and stage of growth of crop at time of each evaluation.
15. Prevalence of target pest present in control and standard comparative treatment areas at the time of each observation of test area, stating the amount of control obtained, and the commercially acceptable level of control.

16. Identification and rating of each type of injury to the crop and to adjacent desirable plants; the duration of each type of injury, and the commercially acceptable level of each type of injury.

Format

When reporting data and procedures involved in the testing of a product, index tabs should be used to separate the sections. If there are a large number of tests within a section, the tests should be subsectioned, according to crop and pest, in the same manner. The data within each subsection should be summarized at the beginning of each subsection. The following format should be used:

Index or table of contents. -- A suitable index or table of contents must be provided at the beginning of the report.

Section A - Name, chemical identity, physical and chemical properties, and complete composition of the product. Include method of analysis if not submitted previously, and production lot number when appropriate.

Section B - Amount, frequency, and time of application of the product, and five copies of the proposed labeling.

Section C - Full reports and data of investigations made with respect to the safety of the product to humans, domestic animals, fish, birds, wildlife, and the environment.

Sections D, E, F, and G - This section is reserved for petitions for residue tolerance only.

Section H - Full reports and data of investigations made with respect to the effectiveness (performance) of the product.

Label Development

Acceptable labeling for a registerable product should evolve from effectiveness data which were obtained in support of (a), proposed directions for the effective use of the product, and (b), precautions which are reflective of acceptable residue, human and wildlife safety, and toxicological data.

FORM APPROVED: BUDGET BUREAU NO. 40-R1746

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

APPLICATION FOR NEW REGISTRATION OF ECONOMIC POISONS

(Under the Federal Insecticide, Fungicide, and Rodenticide Act)

IMPORTANT: READ INSTRUCTIONS ON REVERSE

1. DATE OF APPLICATION

2. NAME OF ECONOMIC POISON *(Must be same product name as on label-do not list active ingredients)*

3. TYPE OF PESTICIDE *(Check each applicable item for combination products)*

INSECTICIDE ☐ FUNGICIDE ☐ HERBICIDE ☐

RODENTICIDE ☐ GERMICIDE–DISINFECTANT ☐

OTHER *(Specify)*

4. NAME & MAILING ADDRESS OF FIRM TO WHOM REGISTRATION IS TO BE ISSUED *(Include Zip Code)*

5. IS THE REGISTRANT SHOWN IN ITEM 4 THE MANUFACTURER?

YES ☐ NO ☐

(If "No", see instruction 5 on reverse)

6. TYPE OF FORMULATION

DUST ☐ WETTABLE POWDER ☐ PRESSURIZED PRODUCT ☐

GRANULAR ☐ EMULSIFIABLE LIQUID ☐ BAIT ☐

OTHER *(Specify)*

7. TYPE OF CONTAINER

METAL ☐ GLASS ☐

PLASTIC ☐ PAPER ☐

OTHER *(Specify)*

8. NET CONTENTS OR CONTAINER SIZES

9. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT

LITHOGRAPHED ☐ PAPER, GLUED ☐ STENCILED ☐

OTHER *(Specify)*

10. PLACE WHERE DIRECTIONS FOR USE APPEAR

ON LABEL ☐ IN PRINTED MATTER ACCOMPANYING PRODUCT ☐

11. DATA SUBMITTED WITH THIS APPLICATION *(Identify and submit in triplicate)*

EFFICACY DATA ☐ TOXICOLOGY DATA ☐ RESIDUE DATA ☐ PETITION FOR TOLERANCE ☐

OTHER *(Specify)*:

12. ANY ADDITIONAL PERTINENT INFORMATION *(Do not enter confidential formula here-see item 13, below)*

13. THE FOLLOWING MUST BE SUBMITTED WITH APPLICATION

- Five (5) copies of proposed labeling, including all printed or graphic matter which may accompany the sale of this product. Copies must be clearly legible and identical.
- Five (5) copies of the complete formula, showing the precise name and percentage of each active and each inert ingredient. *(This information is treated confidentially.)*

14. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE

15. TITLE

16. DATE SIGNED

17. RECEIVED BY USDA – PESTICIDES REGULATION DIVISION, WASHINGTON, D. C.

IN ANY CORRESPONDENCE ON THIS PRODUCT, REFER TO THIS FILE SYMBOL NO.:

PR FORM 9–199
MAY 1969

EXISTING STOCK OF PRFORM 9-199 (JULY 1968) WILL BE USED UNTIL EXHAUSTED

INSTRUCTIONS FOR PR FORM 9–199

ITEM

1. Applications should be submitted as far in advance as possible prior to desired registration date. The time required to process applications may vary, depending on the extent of review required. Applications which require consultation with other governmental agencies will take a longer time to process.

2. The name of the economic poison shown in the application must be the same product name as that shown on the labeling submitted. Do not list the active ingredients.

3. Check or list the type of product for which registration is requested. (Refer to Sec. 362.2 of the Regulation and to Interpretation #3 for definitions.)

4. The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. The address given in item four will be the mailing address permanently on record unless changed by the registrant.

> An applicant NOT residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such agent must accompany this application.

5. If the registrant shown in item 4 is not the manufacturer, and the registrant's name appears on the label, the label must be qualified by appropriate wording such as: : "Packed for....," "Distributed by....," or "Sold by....," to show clearly that the registrant is not the manufacturer.

6–7–8–9. Self Explanatory.

10. Directions for use may be printed on the product label and/or in printed matter distributed with the product.

11. Submit three copies and identify any data to support your application. Enter on application the experimental permit number which may have been issued for testing the product. (Where fish and wildlife may be affected submit four copies of Toxicology Data.)

12. Self Explanatory.

13. Labeling – All copies of labeling must be clearly legible and identical. Photo copy of lithograph labels should be submitted. Do not send containers. Your supplier should be able to furnish photo copies of the screen print. Submit reduced photo copies of large bulky labeling such,as on large printed bags. Any label smaller than half of the size of a sheet of paper 8 inches by 10 inches should be stapled to a sheet of paper 8 inches by 10 inches before attaching to application.

    Formulation – Five copies of a separate statement listing the correct name and percentage by weight of each active and each inert ingredient must be submitted with each application. This statement is treated confidentially. It cannot be used to support a customer's (formulator) application for subsequent registration without written authorization from the registrant. If necessary information on the formula is not available to the applicant (formulator or packer), he should: (a) Obtain the necessary information from the basic supplier and submit five copies of the statement with the application for registration, or (b) Request the basic supplier to furnish the necessary information to the Division along with a statement specifically authorizing the use of such information to support separate registration for the applicant. The statement from the basic supplier must clearly identify the applicant's product to which it applies.

> **ATTENTION:** The submission of an application does not constitute registration. Comment or notice of registration will be sent after examination by the Pesticides Regulation Division of the information submitted.

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

FORM APPROVED
BUDGET BUREAU NO. 40-R1746

APPLICATION FOR AMENDED REGISTRATION OF ECONOMIC POISONS

(Under the Federal Insecticide, Fungicide, and Rodenticide Act)

1. DATE OF APPLICATION

IMPORTANT: READ INSTRUCTIONS ON REVERSE

2. NAME OF ECONOMIC POISON *(Must be same product name as on label—do not list active ingredients)*

3. NAME & MAILING ADDRESS OF REGISTRANT *(Include Zip Code)*

4. REGISTRATION NO.

5. PROPOSED EFFECTIVE DATE OF CHANGE

6. NATURE OF REVISION *(Check applicable item and give details in item 7, when required)*

- ☐ GENERAL REVISION OF LABELING
- ☐ CHANGE IN FORMULATION *(Give description of exact change in item 7)*
- ☐ OTHER *(Specify in item 7)*
- ☐ ADDITIONAL USES ADDED TO LABELING *(List new recommendations in item 7)*
- ☐ CHANGE IN PRODUCT NAME *(Give old name and new name in item 7)*

7. DETAILS REQUIRED BY REVISION CHECKED IN ITEM 6 *(Attach additional sheets if more space is needed)*

☐ CONTINUED ON ATTACHMENT

8. THE FOLLOWING MUST BE SUBMITTED WITH THIS APPLICATION

- Five (5) copies of revised labeling, including any printed or graphic matter which may accompany the sale of this product. Copies must be clearly legible and identical.
- If a change in formulation is involved, five (5) copies of a statement of revised formula showing the precise name and precentage of each active and each inert ingredient. *(This information is treated confidentially)*
- When appropriate, three (3) copies of Supporting Data.

12. RECEIVED BY USDA—PESTICIDES REGULATION DIVISION, WASHINGTON, D. C.

IN ANY CORRESPONDENCE ON THIS PRODUCT REFER TO REGISTRATION NO. IN ITEM 4, ABOVE.

9. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE

10. TITLE

11. DATE SIGNED

PR FORM 9-198
MAY 1969

EXISTING STOCK OF PR FORM 9-198 (AUG. 1968) WILL BE USED UNTIL EXHAUSTED

ITEM

INSTRUCTIONS FOR PR FORM 9--198

1. Applications should be submitted as far in advance as possible prior to desired registration date. The time required to process applications may vary depending on the extent of review required. Applications which require consultation with other governmental agencies will take a longer time to process.

2. The name of the economic poison shown in the application must be the same product name as that shown on the labeling submitted. Do not list the active ingredients.

3. The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. The address given in item three will be the mailing address permanently on record unless changed by the registrant.

4. The registration number assigned must appear on the label. The number must be the same as that appearing on the notice of registration and shall be preceded by the phrase "USDA Registration Number" or the phrase "USDA Reg. No." (Refer to Sec. 362.6(F) of the Regulations)

5. Changes in the labeling or changes in the formula must be submitted in advance of the proposed effective date.

6. Nature of revision -- The registrant must describe the exact changes desired and upon request must submit a description of test results to justify such changes. Minor changes in formulation may be handled as revisions of existing registrations. This might include a change in the percentage of active ingredients or a change in inert ingredients. However, any basic change in formulation such as a change in the principal active ingredients would require a separate registration as a new product with a different product name.

7. Self Explanatory.

8. Labeling -- All copies of labeling must be clearly legible and identical. Photo copy of lithograph labels should be submitted. Do not send containers. Your supplier should be able to furnish photo copies of the screen print. Submit reduced photo copies of labeling for dry agricultural fertilizer - insecticide, or herbicide bags. Any label smaller than half the size of a sheet of paper 8 inches by 10 inches should be stapled to a sheet of paper 8 inches by 10 inches before attaching to application.

   Formulation -- If a change in formulation is involved, five copies of a separate statement listing the correct name and percentage by weight of each active and each inert ingredient must be submitted with each application. This statement is treated confidentially. It cannot be used to support a customer's (formulator) application for subsequent registration without written authorization from the registrant. If necessary information on the formula is not available to the applicant (formulator or packer), he should: (a) Obtain the necessary information from the basic supplier and submit five copies of the statement with the application or (b) Request the basic supplier to furnish the necessary information to the Division along with a statement specifically authorizing the use of such information to support separate registration for the applicant. The statement from the basic supplier must clearly identify the applicant's product to which it applies.

ATTENTION: The submission of an application does not constitute registration. Comment or notice of registration will be sent after examination by the Pesticides Regulation Division of the information submitted.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1970—384-747

FORM APPROVED: BUDGET BUREAU NO. 40-R1746

DEPARTMENT OF AGRICULTURE
ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

APPLICATION FOR RENEWAL REGISTRATION OF ECONOMIC POISONS

(Under the Federal Insecticide, Fungicide, and Rodenticide Act)

IMPORTANT: READ INSTRUCTIONS ON REVERSE

1. DATE OF APPLICATION

2. NAME OF ECONOMIC POISON *(Must be same product name as on label-do not list active ingredients)*

3. TYPE OF PESTICIDE *(Check each applicable item for combination products)*
INSECTICIDE ☐ FUNGICIDE ☐ HERBICIDE ☐
RODENTICIDE ☐ GERMICIDE-DISINFECTANT ☐
OTHER *(Specify)*

4. NAME & MAILING ADDRESS OF REGISTRANT *(Include Zip Code)*

5. REGISTRATION NO.

6. IS THE REGISTRANT SHOWN IN ITEM 4 THE MANUFACTURER?
YES ☐ NO ☐
(If "No", see instruction 6 on reverse)

7. NATURE OF REVISION *(Check each applicable item and give details in item 14, when required)*
GENERAL REVISION OF LABELING ☐
ADDITIONAL USES ADDED TO LABELING ☐ *(List new recommendations in item 14)*
NONE ☐
CHANGE IN FORMULATION ☐ *(Describe exact change in item 14)*
CHANGE IN PRODUCT NAME ☐ *(Give old name and new name in item 14)*
OTHER REVISION ☐ *(Specify in item 14)*

8. TYPE OF FORMULATION
DUST ☐ WETTABLE POWDER ☐ PRESSURIZED PRODUCT ☐
GRANULAR ☐ EMULSIFIABLE LIQUID ☐ BAIT ☐
OTHER *(Specify)*

9. TYPE OF CONTAINER
METAL ☐ GLASS ☐
PLASTIC ☐ PAPER ☐
OTHER *(Specify)*

10. NET CONTENTS OR CONTAINER SIZES

11. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT
LITHOGRAPHED ☐ PAPER, GLUED ☐ STENCILED ☐
OTHER *(Specify)*

12. PLACE WHERE DIRECTIONS FOR USE APPEAR
ON LABEL ☐ IN PRINTED MATTER ACCOMPANYING PRODUCT ☐

13. DATA SUBMITTED WITH THIS APPLICATION *(Identify and submit in triplicate)*
EFFICACY DATA ☐ TOXICOLOGY DATA ☐ RESIDUE DATA ☐ PETITION FOR TOLERANCE ☐
OTHER *(Specify)*:

14. ANY ADDITIONAL PERTINENT INFORMATION *(Do not enter confidential formula here-see item 15, below)*

☐ CONTINUED ON ATTACHMENT

15. THE FOLLOWING MUST BE SUBMITTED WITH APPLICATION
- Five (5) copies of labeling, including all printed or graphic matter which may accompany the sale of this product. Copies must be clearly legible and identical.
- PR FORM 9-196, Confidential Statement of Formula *(This information is treated confidentially.)*

19. RECEIVED BY USDA-PESTICIDES REGULATION DIVISION, WASHINGTON, D.C.

IN ANY CORRESPONDENCE ON THIS PRODUCT REFER TO REGISTRATION NO. IN ITEM 5 ABOVE

16. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE

17. TITLE

18. DATE SIGNED

ATTENTION: The submission of an application does not constitute re-registration. Comment or approval will be sent after examination by the Pesticides Regulation Division of the information submitted.

ITEM

1. Date the application is prepared. The time required to process applications may vary, depending on the extent of review required. Applications which require consultation with other governmental agencies will take a longer time to process.

2. The name of the economic poison shown in the application must be the same product name as that shown on the labeling submitted. Do not list the active ingredients.

3. Check or list the type of product for which registration is requested. (Refer to Sec. 362.2 of the Regulations and to Interpretation #3 for definitions.)

4. The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. The address given in item four will be the mailing address permanently on record unless changed by the registrant.

   An applicant **NOT** residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such agent must accompany this application.

5. The registration number assigned must appear on the label. The number must be the same as that appearing on the notice of registration and shall be preceded by the phrase "USDA Registration Number" or the phrase "USDA Reg. No." (Refer to Sec. 362.6(F) of the Regulations).

6. If the registrant shown in item 4 is not the manufacturer, and the registrant's name appears on the label, the label must be qualified by appropriate wording such as: :"Packed for....," "Distributed by....," or "Sold by....," to show clearly that the registrant is not the manufacturer.

7. Nature of revision - The registrant must describe the exact changes desired, if any, and upon request must submit a description of test results to justify such changes. Minor changes in formulation may be handled as revisions of existing registrations. This might include a change in the percentage of active ingredients or a change in inert ingredients. However, any basic change in formulation such as a change in the principal active ingredients would require a separate registration as a new product with a different product name.

8-9-10-11. Self Explanatory.

12. Directions for use may be printed on the product label and/or in printed matter distributed with the product.

13. Submit three copies and identify any data to support your application. Enter on application the experimental permit number which may have been issued for testing the product. (Where fish and wildlife may be affected submit four copies of Toxicology Data.)

14. Self Explanatory.

15. Labeling - All copies of labeling must be clearly legible and identical. Photo copy of lithograph labels should be submitted. Do not send containers. Your supplier should be able to furnish photo copies of the screen print. Submit reduced photo copies of large bulky labeling, such as on large printed bags. Any label smaller than a sheet of paper 8 inches by 10½ inches should be stapled to a sheet of paper 8 inches by 10½ inches before attaching to application.

    Formulation - Submit PR Form 9-196, Confidential Statement of Formula (original and 4 copies) with each application. If the complete chemical composition of formulated ingredients, either active or inert, used in this product's formulation is not known to you, send a separate set of PR Form 9-196 for each such product to your basic supplier. When you do this, it is important that you first fill in items 2 thru 8 so that we may positively identify the supplier's product with your economic poison. The Basic Supplier is then requested to complete item 1, and items 9 thru 15, and submit the form to this Division. This Statement is treated confidentially. It cannot be used to support a customer's (formulator's) application for subsequent registration without written authorization from the Basic Supplier.

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

CONFIDENTIAL STATEMENT OF FORMULA

(Under the Federal Insecticide, Fungicide, and Rodenticide Act)

FORM APPROVED
BUDGET BUREAU NO. 40-R1746

1. PAGE NO. *This Formula)*

OF

2. DATE OF APPLICATION

IMPORTANT: *Read instructions on reverse before completing form. All information will be treated confidentially.*

3. REASON FOR SUBMISSION *(Check one)*

APPLICATION FOR NEW REGISTRATION ☐ APPLICATION FOR AMENDED OR RENEWAL REGISTRATION ☐ SUBMITTED BY BASIC SUPPLIER *(See instruction C on reverse)* ☐

4. NAME & MAILING ADDRESS OF APPLICANT OR REGISTRANT *(Include Zip Code)*

5. NAME OF ECONOMIC POISON *(Must be same product name as on label-do not list active ingredients)*

6. REGISTRATION NO. OR FILE SYMBOL *(If known)*

7. NAME & MAILING ADDRESS OF BASIC SUPPLIER *(If applicable) (Include zip code)*

8. NAME OF INGREDIENT (PRODUCT) PROVIDED BY BASIC SUPPLIER FOR WHICH FORMULATION IS UNKNOWN *(If any)*

9. IS THE INGREDIENT (PRODUCT) NAMED IN ITEM 8 REGISTERED WITH THE USDA? YES ☐ NO ☐

10. IF "YES" IN ITEM 9, GIVE REGISTRATION NO.

11. NAME OF EACH ACTIVE AND EACH INERT INGREDIENT USED IN THE FORMULATION *(List both the common name and the precise chemical name of each)*	12. PERCENT OF EACH BY WEIGHT
☐ CONTINUED ON ATTACHMENT(S)	All ingredients listed in item 11 above and on additional pages must total →
	100%

13. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE

14. TITLE

15. DATE SIGNED

16. **RECEIVED BY USDA—PESTICIDES REGULATION DIVISION, WASHINGTON, D. C.**

PR FORM 9-196
(MAY 1970)

Who will sign for Air Force

INSTRUCTIONS FOR PR FORM 9-196

A. The complete chemical composition of each economic poison 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.

B. This form is designed for reporting the ingredients used in the formulation of an economic poison. Its use will speed the review. It must be completed and submitted with each "Application for New Registration of Economic Poisons" (PR Form 9-199), or with each "Application for Amended Registration of Economic Poisons" (PR Form 9-198) if revision involves a formula change, or with each "Application for Renewal Registration of Economic Poisons" (PR Form 9-197)

C. If the complete chemical composition of formulated ingredients, either active or inert, used in this product's formulation is not known to you, send a separate set of these forms for each such ingredient to your Basic Supplier. When you do this, it is important that you first fill in items 2 thru 8 so that we may positively identify the supplier's product with your economic poison. The Basic Supplier is then requested to complete item 1, and items 9 thru 15, and submit the form to this Division. This Statement is treated confidentially. It cannot be used to support a customer's (formulator's) application for subsequent registration without written authorization from the Basic Supplier.

ITEM NO.

1. PAGES OF THIS FORMULA. Show "1 of 1", "1 of 2", etc. If space on this form is insufficient to list all ingredients, *continue on additional sheets and number in sequence.*
2. DATE OF APPLICATION. Enter the same date as the related application form.
3. REASON FOR SUBMISSION. Read instruction B above.
4. NAME AND MAILING ADDRESS OF APPLICANT OR REGISTRANT. Enter the name and mailing address of your firm.
5. NAME OF ECONOMIC POISON. Enter the product name of this economic poison as it will appear on the finished label.
6. REGISTRATION NO. OR FILE SYMBOL. These reference items are assigned by the PR Division. If unknown, leave blank.
7. NAME AND MAILING ADDRESS OF BASIC SUPPLIER.
8. NAME OF INGREDIENT (PRODUCT) PROVIDED BY BASIC SUPPLIER FOR WHICH FORMULATION IS UNKNOWN

   Complete only if required by Instruction C above.

9. IS THE INGREDIENT (PRODUCT) NAMED IN ITEM 8 REGISTERED WITH USDA? "YES" or "NO".
10. IF "YES" IN ITEM 9, GIVE REGISTRATION NO. Self-Explanatory.

    Completed only by the Basic Supplier.

11. NAME OF EACH ACTIVE AND EACH INERT INGREDIENT USED IN THE FORMULATION. List both the common name and the precise chemical name of each active and each inert ingredient used in formulating this product.
    a. First list the active ingredients. List them in the very same order as they appear or will appear in the ingredient statement on the finished label.
    b. Next, list the name of each inert ingredient.
    c. When a formulated product is listed in the formula, name its basic manufacturer and give its USDA Registration Number, if known, in parenthesis following the name of the product. (Also see Instruction C above).
    d. The trade name and manufacturer of surfactants and other adjuvants (dyes, emulsifiers, solvents, perfumes) must be listed. The complete chemical composition of emulsifiers and surfactants must be listed. Enclose the manufacturer's name in parenthesis following the product listed by trade name. (Also see Instructions C above).
    e. If a dye or other coloring material is used, state the color.
12. PERCENT OF EACH BY WEIGHT. Enter in this column the percentage by weight of each active and each inert ingredient listed in item 11. Each entry must be opposite that ingredient to which it applies. The percentages by weight for the active ingredients must agree with those appearing in the ingredient statement on the label. The sum of all the percentages listed must equal 100 percent.
13. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE. When completed, the authorized representative of the firm must sign this form.
14. TITLE. Self-explanatory.
15. DATE SIGNED. Self-explanatory.

FORM APPROVED: BUDGET BUREAU NO. 40-R3580

ENVIRONMENTAL PROTECTION AGENCY
PESTICIDES REGULATION DIVISION
WASHINGTON, D. C. 20250

APPLICATION FOR SUPPLEMENTAL REGISTRATION FOR DISTRIBUTORS

(Under Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act)

1. DATE OF APPLICATION

2. REGISTRATION NO.

3. DATE LABELING OF THIS PRODUCT ACCEPTED BY USDA

4. NAME OF REGISTERED PRODUCT

5. NAME AND ADDRESS OF REGISTRANT *(Include Zip Code)*

It is requested that the registration record under the Federal Insecticide, Fungicide and Rodenticide Act of the product named above be amended to include the labels for each distributor listed below:

6. DISTRIBUTOR *(Name and Address - include Zip Code)*	7. DISTRIBUTOR'S PRODUCT NAME *(Show complete product name as it will appear on the distributor's label)*

☐ CONTINUATION SHEET ATTACHED *(If checked, submit 2 copies)*

CERTIFICATION

This is to certify that the distributor(s) product has the same formula as that of the registrant, is manufactured by the same person, and the labeling of which contains the same claims and registration number as the registered product named above. The labeling of this registered product was accepted by the Department of Agriculture by correspondence on the date shown in item 3 above. The product remains in the manufacturer's original unbroken package until it is sold to the user.

8. SIGNATURE OF FIRM REPRESENTATIVE	9. TITLE	10. DATE SIGNED

FOR PESTICIDES REGULATION DIVISION USE ONLY – The registration record under the Federal Insecticide, Fungicide, and Rodenticide Act of the product named above has been amended to include the labels for the distributor(s) listed above.

SIGNATURE	TITLE	DATE

PR FORM 9-1
MAY 1969

EXISTING STOCK OF PR FORM 9-1 (JULY 1968), WILL BE USED UNTIL EXHAUSTED.

GUIDELINES FOR REGISTERING PESTICIDES

SECTION II

GENERAL LABELING REQUIREMENTS

Contents

Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act requires that pesticide products be properly labeled prior to being introduced into interstate commerce. The statutory requirements with respect to labeling are applicable to all economic poisons. These basic requirements are outlined as follows:

Product Name, Brand, or Trademark

There is no prohibition against the use of any name for an economic poison product as long as the name is not misleading. A name is considered to be misleading when (1) a discrepancy exists between the name of the product and the ingredients in the formulation, (2) implications of effectiveness are not provided by the product, or (3) overemphasising (by type size) one ingredient over another. Refer to Interpretation 4 of the Regulations for the Enforcement of the Federal Insecticide, Fungicide and Rodenticide Act for further information in this regard. Generally, the name should be descriptive of the product being offered for sale.

Name of Manufacturer, Registrant, or Person for Whom Manufactured

If the manufacturer's name is not shown on the label, the name used must be qualified by appropriate wording such as "packed for ...," "distributed by ...," or "sold by ..." to show that the name listed is not the manufacturer. For more detail, refer to (CFR 162.2).

Net Contents

The net contents must be given in terms commonly used in the United States. Metric units (or any other) may be listed in addition. Liquid units must be used if the product is liquid and avoirdupois (weight) units if a solid or semisolid.

Pressurized containers must have a declaration of net weight in terms of the largest unit present, but any fractional portion may appear in a smaller unit. For example, declare "two pounds" for a 32-ounce container; "one pound 2 ounces" for an 18-ounce container. An additional statement solely in terms of a smaller unit may also be given. Statements of net contents which comply with the provisions of the Federal Fair Packaging Act are acceptable. Refer also to Interpretation 6 of the Regulations for the Enforcement of the Act.

Ingredient Statement

The label must bear an ingredient statement which usually must be on the front panel. If the size or form of the package makes it impratical

to place the ingredient statement on the front panel, permission may be granted for the ingredient statement to appear elsewhere on the label. If the package contains not more than one pound of a solid or one pint of a liquid, the ingredient statement may appear on the side or back panel. In case the ingredient statement is unusually long, permission may be granted to place it on a side or back panel of packages containing not more than 2-1/2 pounds of a solid or 3 pints of a liquid. In cases where there is an outside wrapper through which the ingredient statement cannot be clearly read, the ingredient statement mus also appear on the outside container or wrapper.

The two permitted forms of ingredient statement are as follows:

(a) ACTIVE INGREDIENT (S)
(Name(s) of Ingredient(s) _____ %

_____ _____ %

INERT INGREDIENT(S) _____ %

(b) ACTIVE INGREDIENT(S)
(Name(s) of Ingredient(s)

_____ _____ %
INERT INGREDIENT(S)

_____

Either form of ingredient statement is in compliance with the requirements of the law; however, option "(a)" is preferred. Option "(a)" must be used for economic poisons highly toxic to man or other animals.

If form "(b)" is used, the names of the active and inert ingredients must, respectively, be listed in the descending order of the percentage by weight of each present, and the names of each ingredient should be given equal prominence. Also, the total percentage of inert ingredients must be provided as well as the formula of the product submitted for our files, (use PR Form 9-196), giving the names and percentages of each ingredient, active and inert.

If form "(b)" is used and all the ingredients are active, the words "Active Ingredients 100%" should head the ingredient statement.

In either form, the words "ACTIVE INGREDIENT(S)" and "INERT INGREDIENT(S)" should be aligned to the same margin.

The correct names of the ingredients (not trade or proprietary names), and their percentages by weight should be given as indicated by the blank spaces. The common name, if there is one, for each active ingredient,

should be used in the Ingredient Statement, followed by the chemical name according to the nomenclature system from Chemical Abstracts. Proprietary names may be referenced to the name in the ingredient statement by use of asterisks. For a list of acceptable names refer to "Acceptable Names for Use in the Ingredient Statement on Economic Poison Labels."1/

With few exceptions, the percentage of each of the active ingredients should be the equivalent amount of the pure material in the product, and not the amount of technical or commercial material. The prominent exceptions are "technical or chlordane," "technical methoxychlor," and "technical piperonyl butoxide."

Ingredient statements for products containing arsenic must have a substatement giving the percentage of total and water-soluble arsenic, each calculated as elemental arsenic.

Warning or Caution Statements

Warning or caution statements which are necessary and, if complied with, adequate to prevent injury to man, beneficial animals, vegetation, and useful invertebrate animals, must appear on labels of economic poison products. Such statements must reflect potential hazards due to ingestion, skin absorption, inhalation, flammability, or explosion of products.

Any substance or substances in quantities highly toxic to man must bear on the label the skull and crossbones, the word "POISON" in red on a contrasting background, and an antidote statement.

Categories of toxicity have been established for economic poison products, based on their toxicity by various types of exposure routes of administration.

The signal word ("Danger," "Warning," or "Caution") and the statement "KEEP OUT OF THE REACH OF CHILDREN" must appear on the front panel of the label in the proper type size. The following table will serve as a guide for the type size requirements on various sized labels:

Size of Label on Front Panel In Square Inches	Signal Word	"Keep Out of Reach of Children"
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

1/ This document is available upon request from the Pesticides Regulation Division, Environmental Protection Agency, Washington, D.C. 20250

Directions for Use

Proper labeling of pesticides must include directions which are adequate for the safe, effective use of the product to protect the public. Generally the directions should include the following information:

(1) The site of application of the economic poison, including such factors as the crops, animals, areas, or objects to be treated.

(2) The rate of application to each site.

(3) Instructions on timing applications to obtain best results and to avoid adverse effects.

(4) Any necessary limitation or restriction such as the time required between application and harvest of food crops; and warnings against the use on certain crops, animals, objects, or in certain areas.

(5) Any other pertinent information which is necessary for the protection of the public.

Directions for use are required whenever they are necessary for the protection of the public. There are cases where detailed directions are not considered necessary. These are spelled out in Interpretation Number 7, (CFR 162.105 (c)).

Generally, the directions for use should appear on the labeling for the pesticide product. Labeling is generally defined as all labels and other printed or graphic matter attached to or accompanying the pesticide product, or to which reference is made on the label or accompanying literature.

Legibility of Labeling

A product is considered misbranded if the labeling is not adequately prominent and conspicuous. All words and statements required to appear on the labeling must be prominently displayed, and presented in terms and with such conspiciousness that would render them likely to be read and understood by the ordinary person. A recent study of pesticide labeling indicated that type size, type form, and print color/background are among the most important factors affecting the legibility of the printed word.1/

In addition to the specific statutory requirements regarding type size for the front panel precautionary labeling, and color for the word "Poison," the general requirements for legibility and

1/ Salcedo, R., Read, H., Evans, J., Kong, A., Achacoso, E., Improving the Communication Adequacy of Pesticide Labels, A Summary Report (December 1970)

comprehensibility must be met. Listed below are some of the suggestions for improving labels which were drawn from the study.

Type Form and Type Face

Avoid printing in all capital letters except for short texts. Print the body of the text in lower case or medley. Use bold letter type to focus attention on key words.

Color Combination of Print and Background

The principle to follow in printing on colored stock is brightness contrast. The greater the brightness contrast, the greater the legibility of the pesticide label. Writers should choose a dark-colored print on a light-colored background. For example, with primary and secondary colors, the following color combinations of print and background are ranked according to brightness contrast:

(a) Violet on yellow (best)
(b) Blue on yellow
(c) Violet on orange
(d) Blue on orange
(e) Red on yellow
(f) Green on yellow
(g) Violet on red
(h) Violet on green
(i) Blue on red
(j) Red on orange
(k) Green on orange
(l) Blue on green
(m) Violet on blue
(n) Orange on yellow
(o) Green on red
(p) Red on green (worst)

Note: Another classification of color combinations, found in at least three studies in the review of literature accompanying the study, provides even greater flexibility for the label maker. This classification includes black and white, and provides a greater range of brightness contrast than the previous classification (black on yellow produces a greater brightness contrast than violet on yellow):

(a) Black on yellow (best)
(b) Green on white
(c) Red on white
(d) Blue on white
(e) White on blue
(f) Black on white
(g) Yellow on black
(h) White on red
(i) White on green
(j) White on black
(k) Red on yellow
(l) Green on red
(m) Red on green (worst)

Indention of Paragraphs

Paragraphs should be indented for increased legibility.

Advertising

Advertisements should not be included on pesticide labels since they would take the place of more important information.

Disclaimer Statements

Labeling disclaimers which negate or distract from required labeling information are not acceptable.

An example of an unacceptable disclaimer is the following statement:

> "The information furnished hereon is provided gratuitously by the manufacturer, who assumes no responsibility whatsoever for the effectiveness or safety of this product, regardless of whether or not it is used as directed."

There is no objection to statements that are aimed at protecting the seller against damages from careless or improper handling, or use, as long as they are not false or misleading.

Examples of Disclaimer Statements Which Are Not Objectionable

1. Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material, when such use and/or handling is contrary to label instructions.

2. Follow directions carefully. Timing and method of application, weather and crop conditions, mixtures with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herewith.

3. Buyer assumes all risks of use, storage, or handling of this material not in strict accordance with directions given herewith.

4. Seller's guarantee shall be limited to the terms of the label, and subject thereto, the buyer assumes any risk to persons or property arising out of use or handling, and accepts the product on these conditions.

5. Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such, or the results to be obtained, if not used in accordance with directions or established safe practice. The buyer must assume all responsibility, including injury or damage, resulting from its misuse as such, or in combination with other materials.