Label Review Manual

Chapter 5

INGREDIENT STATEMENT

I. INTRODUCTION

This chapter covers the ingredient statement and footnotes sections of the label, which must contain, as provided in 40 CFR 156.10(g), the name and percentage by weight of each active ingredient, the total percentages by weight of all "Other Ingredients," and substatements including, but not limited to: the acid equivalent, elemental equivalent, toxic ingredients, petroleum distillates, sodium nitrite, and corrosivity. If the pesticide contains arsenic, in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. 40CFR 156.10(g)

II. WHAT IS INCLUDED IN AN INGREDIENT STATEMENT

A. FORMAT. The label reviewer must review the proposed label for a clear and prominent ingredient statement which contains the name and the percentage of each active ingredient, and the total percentage of all "inert" or "other" ingredients, in the pesticide and if arsenic is present, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. 40 CFR156.10(g). The ingredient statement must be presented clearly, and be neither obscured nor crowded by surrounding text. 40 CFR 156.10(a)(2) and (ii). Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" must not be used as a heading for the ingredient statement. 40 CFR 156.10(g)

B. ACTIVE INGREDIENT. Under 40 CFR 152.3, active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel, or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant, within the meaning of FIFRA section2(a), except as provided in 40 CFR 174.3.

C. INERT INGREDIENT. Under 40 CFR 152.3, inert ingredient means any substance (or group of structurally similar substances if designated by the Agency) other than an active ingredient which is intentionally included in a pesticide product, except as included in 40 CFR 174.3. Some examples of ingredients that may be inert ingredients include: solvents, stabilizers, spreaders or stickers, preservatives, surfactant, defoamers, etc.

1. PR Notice 97-6 sets forth the Agency's policy concerning the use of "inert" on the label ingredients statement. Under this policy, applicants and registrants are permitted to substitute the heading "Other ingredients" for the heading "Inert ingredients."

D. CONTENTS. The name and nominal concentration expressed as a percentage by weight of each pure active ingredient must be placed under the ACTIVE INGREDIENT heading and the total percentage by weight of all inert/other ingredients must be placed under the heading INERT INGREDIENT or OTHER INGREDIENT (or plural forms of these terms when appropriate).

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E. HEADINGS. The headings "ACTIVE INGREDIENT" and "OTHER [INERT] INGREDIENT" (or plural forms of these terms when appropriate), must be the same type size, aligned to the same margin and equally prominent. PR Notice 97-6 recommends "OTHER INGREDIENT" instead of "INERT INGREDIENT," but either may be used. Additionally formatting requirements are set out at 156.10(g)(2)(ii) which provides that the "text of the ingredient statement run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text."

F. PERCENTAGES. The percentages shall be stated in terms of weight-to-weight and the sum of percentages of active and inert ingredients shall be 100. Percentages shall not be expressed by a range of values as 22-25%. 40 CFR 152.10(g)(4). The percentages of active and other ingredients must be aligned by the decimal point.

G. EXPANDED INERT STATEMENTS. Registrants are encouraged to disclose on the label the inert/other ingredients in their pesticide product either by chemical name or functional category with a brief explanatory definition with percentage. For example:

H. It is recommended that the percentage of active and other ingredients be aligned by the decimal point.

III. LOCATION OF INGREDIENT STATEMENT

A. FRONT PANEL. The ingredient statement is normally required to appear on the front panel of the label unless the Agency determines that doing so is impractical. Some examples might be if the pesticide package is extremely small or irregular in shape to the point of making it difficult to place the ingredient statement on the front panel of the label. In such cases, permission may be granted, upon written request (as part of the application), for the ingredient statement to appear on the back or side panel of the label. See 40 CFR 156.10(g)(2)(i).

B. LOCATION ON FRONT PANEL. The preferred location for the ingredient statement is immediately below the product name. (Refer to the sample label formats in chapter 3).

C. OUTSIDE WRAPPERS. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on the outside container or wrapper. See 40 CFR 156.10(g)(2)(i).

IV. NAMES TO BE USED IN THE INGREDIENT STATEMENT

A. FIRST STEPS. The label reviewer must review the names for ingredients used on the proposed label and cross-reference the names in the OPPIN database on the LAN. If none of the

names are included in OPPIN, perhaps the chemical name of the active ingredient is new or the registrant used an inappropriate name. If so, check with your PM/team leader for the correct procedures to follow. Look at each section below to determine the correct names to be used in the ingredient statement.

B. COMMON NAME

1. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. 40 CFR 156.10 (g)(3). Through PR Notice 97-5, the Agency clarified what it considers as acceptable common names. EPA will permit the use of common names approved by the American National Standards Institute (ANSI) in the label ingredients statement without the accompanying scientific chemical names, and will permit the use of other common names listed in PR Notice 97-5 without the accompanying scientific chemical name. When a common name only appears on the label, EPA also recommends the inclusion on labels of Chemical Abstracts Service (CAS) numbers to identify ingredients definitively.

2. The label reviewer should check OPPIN to determine the accepted common name. "(ANSI)" or a "C" in the TYPE column will be shown with the accepted common name in the Chemical Name list. An additional source for this information on older chemicals is the EPA publication, *Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels*, 4th edition (December 1979).

3. A list containing some of the common/chemical names may also be found in the Pesticide Tolerance Commodity/Chemical Index section in the back of the CFR volume containing the FIFRA regulations 40 CFR 150-189. Because this list only includes names for chemicals with tolerances, it is only a secondary source. Similarly, a list of some common/chemical names can be found in PR Notice 97-5.

C. CHEMICAL NAME

1. If the active ingredient has a common name, but not one that is considered "accepted" the full chemical name must be used in conjunction with a common name 40 CFR 156.10(g)(3). For example:

Acephate (0,S-dimethyl acetylphosphoramidothioate)

2. EPA requests that chemical names be consistent with the nomenclature used in the Chemical Abstracts (CA) Chemical Substance Index, published by the American Chemical Society. OPPIN reflects the correct chemical name: the entry found with the "9CI" (i.e., Ninth Collective Index) designation at the end of the name. [*OPPIN tip for label reviews*: hit the Enter key on the chemical name to see the complete chemical name, which may not appear on the line if the name is too long to fit on the line.]

D. CAS (CHEMICAL ABSTRACTS SERVICE) NUMBER. The CAS number for the active ingredient(s) may be used on the label in connection with the ingredient statement. If the CAS number is used, it should appear as a sub-statement (footnote) to the ingredient statement and not in any way detract from the ingredient statement.

E. MICROBIAL NAME. If the active ingredient is a microbial agent, the Agency requests that the microbial agent be identified by genus and species (and if appropriate also by subspecies and/or isolate number). Again, this name should be identical to the name shown in REFS.

F. DESCRIPTIVE NAME. Descriptive names approved by the Agency may be used in the ingredient statement if there is no accepted common name and no distinctive chemical name. Examples are: "Tobacco dust," "Egg solids," or "Dried blood." Approved descriptive names are listed in REFS, and the name shown on the proposed label must be identical to the name found in REFS.

G. TRADEMARK NAME. A trademark or proprietary name may not be used in the ingredient statement unless it has been accepted as a common name by the Administrator under the authority of FIFRA Section 25(c)(6). See 40 CFR 156.10(g)(3).

V. CRITERIA FOR DETERMINATION OF PESTICIDAL ACTIVITY

A. IS THE INGREDIENT CONSIDERED TO BE ACTIVE

1. The criteria for determination of an ingredient's active or inert status are located in 40 CFR 153.125 and PR Notice 81-4. Generally speaking an ingredient will be considered an active ingredient if, by itself, and when used as directed at the proposed use dilutions, it has the capacity to function as a pesticide or has the ability to elicit or enhance the effect of another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Ingredients such as stickers and other adjuvants which function simply to enhance or prolong the activity of an active ingredient by physical action are not generally considered to be active ingredients.

2. A chemical may be an active ingredient in one formulation and an inert ingredient in another. Examples are chemicals used as preservatives of a formulation, plant nutrients, or chemicals with some other non-pesticidal use.

B. RELATED COMPOUNDS (ACTIVE). As described in PR Notice 81-4, EPA recommends that related compounds that are now distinguishable from the intended active ingredient(s) due to newer, more discriminating methods of analysis must be accounted for within the pesticide label ingredients statement. If one or more related compounds is isolated and found to have pesticidal activity to the target pest, EPA requests that it be specifically identified and quantified by percentage under the ACTIVE INGREDIENT heading of the label ingredients statement. For example:

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ACTIVE	INGREDIENTS
TOTIC	monupling.

2-Carbomethoxy-1-methylvinyl dimethyl phosphate, α isomer	
2-Carbomethoxy-1-methylvinyl dimethyl phosphate, β isomer	
OTHER INGREDIENTS:	
Total	

C. RELATED COMPOUNDS (INERT). Related compounds whose active/inert status is not determined by the registrant, must be included (without designation as related compounds or by name) under the total percentage of the INERT INGREDIENT or OTHER INGREDIENT heading (see PR Notice 81-4).

D. EQUIVALENTS: Unless declared as an active ingredient, a related compound must not be included in expressing percent acid or metallic equivalents, nor in the declaration of "pounds active ingredient" or "acid (or metallic) equivalents per gallon" under the ingredient statement. (PR Notice 81-4).

VI. STATEMENT OF CONCENTRATIONS

A. DEFINITION. The percent nominal concentration specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). The nominal concentration is the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight. The nominal concentration is the <u>only acceptable method for expressing</u> the percentage of active ingredient in the product. All pesticide ingredient statements must be expressed as nominal concentration.

B. EXPRESSIONS

1. Reviewers of proposed labels for products subject to deterioration, such as sodium hypochlorite, should note Section IX (Deterioration), below.

2. The percent of the pure active ingredient in a technical grade product is the same as its nominal concentration. This must be indicated in Columns 10 and 13b of the CSF.

3. The nominal concentration in a formulated product is a function of the percentage by weight of the active ingredient in the product (including associated ingredients) and the purity of the source product (its nominal concentration). For example:

If the purity of the active source is 80%, as declared in column 10 of the CSF, and the percentage by weight of the active ingredient in the formulated product is 20% as indicated in column 13(b) of the CSF, the nominal concentration of the product would be 16% (20% x 0.80), consistent with the label claim. The 16% nominal concentration can be indicated between parentheses in the same column below the 20%w/w.



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4. If wider limits for active and inert ingredients were justified as per the regulations 40 CFR 158.175 (c) which case the proposed upper and lower certified limits must be indicated on the Confidential Statement of Formula (CSF) and the guarantee of each active ingredient in percent must be indicated on the label. The guarantee is the label claim nominal concentration, a value between the upper and lower certified limits, not equal to either value.

5. The sum of the percentage by weight of the active ingredient and intentionally added inert/other ingredients in a formulated product must be equal 100%. In a technical grade of active ingredient, the total of all nominal concentrations of the pure ingredient plus associated ingredients, including impurities, must be $\ge 98\%$.

6. For ingredient statements which reflect the fact that the active ingredient is the only component of the product, the inert ingredients header is not necessary. For example, for a product which is 100% pure chlorine gas, the following ingredient statement is acceptable:

ACTIVE INGREDIENT: Chlorine......100.0%

Assuming that the chlorine gas is only 99% pure, then the following ingredient statement would be required:

7. If the proposed label is for a liquid formulation, the label reviewer must check the Directions For Use section. If any of the use directions of the pesticide product are expressed as a certain weight of active ingredient per unit area (such as pounds per acre), a statement of the weight of the active ingredient per unit volume of the pesticide formulation must also appear at the end of the ingredient statement. See 40 CFR 156.10(g)(4). This is very important when calculating the use rates. An example of this would be, "One gallon contains 4 pounds of the active ingredient (chemical)." If dosage rates in the directions for use are expressed as weight of product/unit area, the weight of the product/gallon must be stated.

VII. SUBSTATEMENTS (FOOTNOTES)

Based on historical practice, EPA requests the following footnotes appear on the label, as applicable:

A. PETROLEUM DISTILLATES. Products containing petroleum distillates, xylene or xylene range aromatic solvents at $\geq 10\%$ should be indicated on the label immediately below the ingredient statement as a footnote below the term "Inert ingredients" or "Other Ingredients" as follows:

"Contains petroleum distillates, xylene or xylene range aromatic solvents."

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B. INGREDIENTS OF TOXICOLOGICAL CONCERN. Products containing ingredients of toxicological concern should be indicated on the label immediately below the ingredient statement as a footnote below the term "Inert Ingredients or "Other Ingredients" as follows:

"This product contains the toxic ingredient (name of ingredient), at ...% (indicate the upper certified limit of the toxic component in percent).

C. SODIUM NITRITE. Products containing sodium nitrite at >0.1% should indicate in the ingredient statement as a footnote below the term "Inert Ingredients" (or "Other Ingredients") as follows:

"This product contains sodium nitrite."

VIII. DETERIORATION

A. GENERAL LABELING. In cases where it is determined that a pesticide formulation changes chemical composition significantly over time, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]." (40 CFR 156.10(g)(6)(i)) Note the product must meet all label claims up to the expiration time indicated on the label.

B. SODIUM HYPOCHLORITE. For sodium hypochlorite products containing 5.25 - 12.5% active ingredient, the Agency historic practice has been that instead of an expiration date on the label, the following labeling statement is necessary to ensure the product is effective (because of its rapid degradation).

"Degrades with age and exposure to sunlight and heat. Use a test kit and increase dosage as necessary to obtain the required level of available chlorine."

IX. SPECIFIC DESIGNATIONS FOR SOME INGREDIENT STATEMENTS

A. Some pesticide ingredients require specific designations on the ingredient statement for proper clarification and identification. Examples of some of these specific designations are shown below:

1. Microbial Pesticides. Biopesticides are generally subject to the same labeling provisions as conventional pesticides. They are viewed essentially the same as chemical pesticides with respect to label requirements, except for differences with the ingredient statement.

a. Products containing live microorganisms the agency has historically required that the label indicate the equivalent number of viable units (spores, cells, colony forming units, etc.) per unit weight or volume of product.

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b. For <u>Bacillus thuringiensis</u> (Bt) products, the Agency has historically required the following labeling information. The active ingredient declaration must be based upon percent by weight of insecticidal toxin(s) present. Strain variety, as well as percent active ingredient declared for each order of insects affected, must appear on the label. (PR Notice 72-6). The use of potency units expressed in terms of International Units (IU) per milligram of product is required unless the percent toxin has been shown to predict field activity. If used, it should appear on the label below the ingredient statement and should be followed by the statement "Potency units should not be used to adjust use rates beyond those specified in the Direction for Use section." For example:

ACTIVE INGREDIENTS:

 Bacillus thuringiensis subspecies kurstaki

 Lepidopteran active toxin
 3.0%

 Dipteran active toxin(s)
 2.0%

 OTHER INGREDIENTS:
 95.0%

 Total
 100.0%

 Potency:
 40,000 International Units per milligram of this product. Potency units should not be used to adjust rates beyond those specified in the Directions for Use section.

Because the reregistration data on percentage of active ingredients have not been reviewed for Bt products, labels for many Bt products still list the percentage a.i. based on potency. For potency based ingredient statements for lepidopteran active Bt products, would indicate 500,000 International Units (IU)/mg product = 100% active ingredient. Percent active ingredient is calculated on the product potency compared to the 100% active ingredient assumption of 500,000 IU/mg. Thus, a 16,000 IU/mg product would be (16,000/mg) x (100%/500,000 IU/mg) = 3.2.%.

(1) Subdivision M (Pesticide Testing Guidelines) Microbial and Biochemical Pest Control Agents (July 1989) addresses this topic. Certified limits can be expressed as:

(a) Microbial Pest Control Agents (MPCA) units/unit weight or volume

(b) International Units of Potency per unit weight

(c) Weight percent of product

Items (a) and (b) may be expressed using biological, genetic, biochemical, serological or other appropriate data. For example:

ACTIVE INGREDIENT:	
Pseudomonas cepacia type Wisconsin	3.8% (by wt.)
OTHER INGREDIENTS:	<u>96.2%</u> (by wt.)
Total	100.0% (by wt.)

Contains at least 50 million viable cells/lb (10⁵ cells/gram).

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ACTIVE INGREDIENTS:Trichoderma harzianum (ATCC 20476)16.6% W/WTrichoderma polysporum (ATCC 20475)16.6% W/WOTHER INGREDIENTS:66.8.% W/WTotal100.0% W/W

Minimum 4.5 million colony forming units (CFU) per pound (454 grams)

2. **Biochemical Pesticides**. The ingredients statement for a product for which the active ingredient is a naturally occurring plant regulator, (such as cytokinins, auxins, or gibberellins) and for which quantitative chemical methods and units are not available, must be stated in an acceptable and generally recognized bioassay unit. For example:

ACTIVE INGREDIENT:	
Cytokinin (equivalent to 200 ppm kinetin activity)	3.0%
OTHER INGREDIENTS:	97.0%
Total	100.0%

3. **Pheromone Products**. The ingredient statement for pheromone dispenser labels shows the pheromone in mg. per dispenser as a footnote. This must be as reflected in the CSF.

ACTIVE INGREDIENT:	
Pheromone*	1.0%
OTHER INGREDIENTS:	99.0%
Total	100.0%
*x mg per dispenser	

4. Insect Virus-based Insecticides. Pesticide products containing an insect virus as the active pesticide ingredient must indicate the number of activity units (polyhedral inclusion bodies for nuclear polyhedrosis viruses or capsules for granulosis viruses) per gram (10⁶ PIBS/gm) or percentages (%). For example:

BIOCONTROL-1

Biological Insecticide for the Control of Douglas Fir Tussock Moth

Often the active ingredient statement will include "... and insect body parts..." whether the baculovirus is propagated in vivo or in vitro. For example:

SPECIFIC-T-1

ACTIVE INGREDIENT:Granulosis Virus of Cydia Pomonella (Coddling Moth)(at least 5 x 108 GIBS/ml)0.005%OTHER INGREDIENTS:99.995%Insect parts/water/inert solids99.985%Aureomycin (5.5%)0.015%Total100.000%

5. Salts, Amine or Ester of Acids. If the active ingredient is a salt, amine or ester of an acid, the label must declare in a substatement under the ingredient statement the percentage equivalent of the acid. For example:

ACTIVE INGREDIENTS:	
Isooctyl ester of 2,4-Dichlorophenoxyacetic acid*	12.0%
Isooctyl ester of 2-(2,4-Dichlorophenoxy) propionic acid**	10.0%
OTHER INGREDIENTS:	<u>78.0%</u>
Total 1	00.0%
*2,4-Dichlorophenoxyacetic acid equivalent, 9.5%	
**2-(2,4-Dichlorophenoxy)propionic acid equivalent, 9%	

6. Copper and Zinc Salts or Complexes. Pesticide products for which the active ingredients are copper salts or complexes must declare the chemical name of the copper complex as active ingredient and the equivalent metallic copper declared in a substatement. For example:

ACTIVE INGREDIENT:	
Copper naphthenate*	
OTHER INGREDIENTS:	
Total	
*Metallic copper equivalent, 22%	

This type ingredient statement declaration is also applicable to zinc. For example, zinc naphthenate must be expressed as percent metallic zinc equivalent.

7. Brominated and/or Chlorinated Compounds. Certain brominated or chlorinated compounds may require a reference in the ingredient statement to the available chlorine or bromine. For example:

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ACTIVE INGREDIENT:

1-Bromo-3-chlo	ro-5, 5-dimethylhydantoin 86.4%	6
1-3dibromo-5, 5	-dimethylhydantoin 8.69	%
OTHER INGRI	DIENTS:	6
Total		%
Provides:	66.8% Available Bromine	
	25.4% Available Chlorine	

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8. Metal Ion Exchange Resins: Any metal (e.g., Ag or Cu) used as pesticide, when bound to an ion exchange resin, must be declared on the label as the percent metallic equivalent with a footnote immediately below the ingredient statement specifying the identity and amount of the ion exchange resin which was used.

9. Sodium Chlorate Products: Because sodium chlorate is extremely flammable, all pesticide products containing sodium chlorate must include a fire retardant in the formulation. These labels must bear in the vicinity of the ingredient statement, a statement indicating that the product contains a fire retardant. If the proposed label is a sodium chlorate product, check the CSF to verify that the product contains a fire retardant (column 15, Purpose in Formulation).

10. Arsenic Containing Products: Pesticide products which contain arsenic in any form must include a substatement of the percentages of total arsenic and water-soluble arsenic calculated as elemental arsenic. See 40 CFR 156.10(g)(1). For example:

"Total arsenic, all in water soluble form, expressed as elemental = xx%"

11. **Products with Petroleum Distillates**: Formulations containing greater than or equal to 10% petroleum distillates, xylene, or xylene range aromatic solvent must reflect the statement "Contains petroleum distillates, xylene, or xylene range aromatic solvent" immediately below the ingredient statement as a footnote to the inert ingredients.

12. Fertilizer-pesticide Combinations: Pesticides that are formulated in combination with fertilizers must bear an ingredient statement the same as any other pesticides. The fertilizer composition must be separate from the pesticide ingredient statement and must not detract from or obscure the required pesticide labeling statements.

13. Complexing Agents: In products containing an active ingredient bound with other agents as a complex, the active ingredient, must be declared in the ingredient statement with a footnote immediately below the active ingredient statement listing the complex formed. In the case of complexed iodine, for example, the active ingredient is titratable iodine.

ACTIVE INGREDIENT:	
Iodine*	. 15.0%
OTHER INGREDIENTS:	. 85.0%
Total	100.0%
*from (name of complexing agent)	

X. INERT INGREDIENTS

A. SPECIAL LABELING REQUIREMENTS FOR INERTS OF TOXICOLOGICAL CONCERN (LIST 1). Products containing one or more other/inert ingredients on List 1 (inert ingredients of toxicological concern) have historically been required to include on the label the statement: "This product contains the toxic inert ingredient (name of inert)." See Inert Ingredients in Pesticide Products; Policy Statement OPP-36140;FRL-3190; 40 CFR 156(g)(7). This statement must be placed in close proximity to the ingredient statement in a type size comparable to other front

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panel text. (Refer to chapter 13 also) For enforcement purposes applicants have been asked to indicate on the label the "maximum" percent of ingredients of toxicological concern characterized in the product. PR Notice 90-1, issued May 1, 1990, revised and modified previous published lists

of inert ingredients in pesticide products that are of toxicological concern and require priority testing. In general, after the PR Notice was issued EPA did not register any new products containing a List 1 inert. The most current inert list is available on the

Web: http://www.epa.gov/opprd001/inerts. The list of seven inert ingredients is as follows:

CAS No.	Chemical Name
50-00-0	Formaldehyde
78-59-1	Isophorone
81-88-9	Rhodamine B
108-95-2	Phenol
117-84-0	Diocytl phthalate
123-31-9	1,4-benzendiol
25154-52-3	Nonylphenol

LIST 1. -- INERTS OF TOXICOLOGICAL CONCERN

B. IDENTIFICATION OF INERT/OTHER INGREDIENTS. Inert ingredients are not required to be identified individually in the ingredient statement except when EPA determines that such inert ingredient may pose a hazard to man or the environment. See 40 CFR 156.10(g)(7). In such a situation, EPA may require that the name of the inert be listed in the ingredient statement. However, if a registrant wants to list a particular inert ingredient in the ingredient statement the registrant must list **all** inert ingredients directly below the ingredient statement.

XI. ALTERNATE FORMULATIONS

A. EPA may approve a basic formulation and one or more alternate formulations for a single product. An alternate formulation must meet the criteria listed in 40 CFR 152.43(b)(1) through (4). The Agency may require the submission of data to determine whether the criteria have been met. Registrants are encouraged to keep their alternate formulas, if any, up-to-date. The label text of the alternate formulation product must be identical to that of the basic formulation. The Agency will not approve an alternate formulation if the alternate formulation requires a change in the label text.

B. The alternate formulation must have the same certified limits for each active ingredient as the basic formulation. 40 CFR 152.43(b)(1)

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C. If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation.

D. The analytical method required under 40 CFR 158.180 must be suitable for use on both the basic formulation and the alternate formulation.

E. Alternate formulas, should be clearly marked "Alternate Formula A," "Alternate B," etc. Further, indication that an alternate formula is replacing "alternate formula x" or "is in addition to "alternate formula y" would reduce confusion.

F. Except for approved dye substitutions, EPA does not accept alternate formulations for rodenticides.



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Hiami Products & Chemical Co. 520 Lonoke St. Dayton, Ohio 45403

Gentlemen:

Subject :

SANYGEN File Symbol 278-US Your application of October 7, 1974

The product referred to above will be acceptable for registrationunder the Federal Insecticide, Fungicide, and Rodenticide Act: provided, finished labeling is submitted.

"EPA Reg. No. 278-43" is being reserved for this product. This must appear on the finished label. The "Notice of Registration" will be issued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished lableing.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

Sincerely,

BEST DOCUMENT AVAILABLE

12 NOV 1974

Richard F. Mountfort CFM Section Head Fungicide-Harbicide Branch

2 Enclosures

A-79 Duplicate ltr.

ABPR:RFM:dj 11-11-74

COMPLAINANT EXHIBIT No. 2





January 7, 1975

Mr. Richard F. Mountfort Section Head Fungicide-Herbicide Branch U. S. Environmental Protection Agency Washington, D. C. 20460

Dear Mr. Mountfort:

We are enclosing copies of our finished labeling for our product SANYGEN, EPA Reg 278-43, File Symbol 278-UG.

COMPLAINANT EXHIBIT No. 3

0017

Thank you for your assistance in helping us register this label.

Sincerely

THE MIAMI PRODUCTS & CHEMICAL CO.

William H. Focke President

WHF:mrb Enclosures











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DIRECTIONS

For newly filled pools or pools that are started up in the spring add the amount of SANYGEN indicated for your size pool. In areas where the water is hard, containing a high amount of minerals, this could cause staining of the pool. It is recommended to add a chemical sequestrant before adding SANYGEN. If one is not available add the SANYGEN slowly over a period of 2 to 3 days.

added. Test the water frequently for a chlorine residual of between 0.6 to 1.0 ppm. Add % of the daily dosage in the morning and % in mid-afternoon or as in 5,000 gallons of water. However, chlorine is used up and more will be Follow the application chart for the daily dosage after the initial dosage is needed when indicated by a test set. Hot sunny days and heavy bather loads will require more frequent tests and additions of SANYGEN to maintain proper chlorine residual. Six ounces of SANYGEN will give you 1.0 ppm of chlorine required to maintain a constant chlorine residual. Use a test set to determine the PH of your water. Maintain the PH between 7.2 and 7.6. Add muratic acid or dry acid to lower the PH. Add soda ash to raise the PH.

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ACT

Superchiorinate every 2 weeks or when algae is present. Use the two weeks dosage chart to determine the amount of SANYGEN to add. Always add after the swimmers are out of the pool in the evening. After superchlorinating, test water prior to swimming to make sure chlorine residual is not excessive, over 1.5 ppm.

APPLY THIS PRODUCT ONLY AS SPECIFIED ON THIS LABEL. Buyer assumes all risk of use of this chemical if used contrary to directions. **NOTICE:**

Manufactured by MIAMI PRODUCTS & CHEMICAL CO. Dayton, Ohio 45403

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			DOSAGE	CHART	
		Swimming	Initial	DAILY	Docepe
		Pool	Treatment	Dosage	Aleve C
			CANVCEN	OT CANVEEN	SANYCEN
	Net Co cents				
		5,000	½ gallon	X gallon	½ galion
	ONE GALLON	10,000	1 gallon	% gallon	1 gallon
		20,000	2 gallons	1 gallon	2 gallons
		30,000	3 gallons	1% gallons	3 gallons
		40,000	4 gallons	2 gallons	4 gellons
		50,000	5 gallons	2% gallons	5 gallons
		HOW TO E	STIMATE GALLON	CAPACITY OF YC	JUR POOL
		Measure Ler	ngth (L), Width (W),	and average Depth	(D), in feet.
			For Square or Re	sctangular Pools: 2.5 = Gallons	
<i>2.</i> ,	0		For Circular or I	Elliptical Pools: 0.9 = Gallons	
	0:	CAUTION: Harm	ful if swallowed. A	void contact with a	skin and eyes. May
		Cause	severe skin and eye	irritations. In case o	of contact with skin
	5	and	yes flush with plenty	/ of water. If irritation	on develops, contact
			sician.		
		FIRST AID: Exter	nal, flood with cold	Water. If irritation	Develops, contact a
		inter (cian. nal feed raw eoo wh	hite. milk or cooked	d cereal followed by
	ε.	olive	oil or cooking oil. C	ontact a physician.	
		When container is e	mpty rinse thorough	ly with water and di	isard.
		Degrades with age.	Use a test kit and	increase dosage as	necessary to obtain
		required chlorine re	sidual.		
		This product is toxi	c to fish. Treated eff	fluent should not be	discharged where it
a	EPA Rep. No. 278-43	will drain into lakes,	streams, ponds, or pi	ublic water.	

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U.S. ENVIRONMENTAL PROTECTION AGENCY	EPA REGISTRATION NUMBER
OFFICE OF PESTICIDES PROGRAMB REGISTRATION DIVISION	
WASHINGTON, D.C. 20480	February 10, 1975
	NAME OF PESTICIDE PRODUCT
NOTICE OF REGISTRATION (Under the Pederal Insecticide, Fungicide, and Rodenticide Act, as amended)	SANYGEN
NAME AND ADDRESS OF REGISTRANT Niemi Products & Chemical Co. 520 Lonoke Street Dayton, Ohio 45403	
L. NOTE: Changes in labeling or formula differing in substance from the	wt accepted in connection with this registration must h
mitted to and accepted by the Registration Division prior to use of always refer to the above EPA registration number.	the label in commerce. In any correspondence on this p
On the basis of the information furnished by the registran under the Federal Insecticide, Fungicide, and Rodenticide A	t, the above named pesticide is hereby registered et.
A copy of the labeling accepted in connection with this re-	gistration is returned herewith.
order to protect health and the environment, the Administrato the registration of a pesticide in accordance with the Act. The gistration of a product under this Act is not to be construed a name or to its use if it has been covered by others.	ent or approval of this product by this Agency. If r, on his motion, may at any time suspend or can be acceptance of any name in connection with the as giving the registrant a right to exclusive use of add
The registration for this product is being issued with	the understanding that certain defects in the lab
which are noted below will be corrected as soon as p present labeling for a reasonable period of time while copies of the corrected labeling must be submitted.	ossible. Objection is not raised to the use of the fully corrected labeling is being prepared. Three
which are noted below will be corrected as soon as p present labeling for a reasonable period of time while copies of the corrected labeling must be submitted.	ossible. Objection is not raised to the use of the fully corrected labeling is being prepared. Three
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which are noted below will be corrected as soon as p present labeling for a reasonable period of time while copies of the corrected labeling must be submitted.	ARC A. E. Castillo Product Hanager (34)
which are noted below will be corrected as soon as p present labeling for a reasonable period of time while copies of the corrected labeling must be submitted. AEC:r BEST DOCUMENT AVAILABLE Attachment is applicable.	ACC A. E. Castillo Product Hanager (34) Disinfectants Brauch (AH-467)
which are noted below will be corrected as soon as p present labeling for a reasonable period of time while copies of the corrected labeling must be submitted. AEC: BEST DOCUMENT AVAILABLE DEST DOCUMENT AVAILABLE Mattachment is applicable.	ARC A. E. Castillo Product Hanager (34) Disinfectants Brauch (24-567)



Registration #	Name	Status	Restricted Use Product	Company #	Company Name	Percent Active Ingredient	Active Ingredient
278-43	SANYGEN LIQUID SHOCK	Registered (03-Feb- 1975)	N	278	MIAMI PRODUCTS & CHEMICAL COMPANY	10.5	Sodium hypochlorite

Summary Report

COMPLAINANT EXHIBIT No. 5



dis full a folg DIRECTIONS for use, It is a violation of foreral law to use this product in a manner inconsistent with - 3 2

ordans the responed test of available chloring MOTE. This product degrates with age. Use a chilorine test kit and increase dosage, as necessary, to

STOHAGE and disposal Unite this privility in a civil sty area, away from direct surflight and heat to of cy, apriced tainer that place in trash cullectrist. (2) in Ecristaminate food or feed by storage, disposal or cleaning can to d be used should be didnly with water before dissosation a samilary sewer. Do not reuse conassered to be notation. In tasse of spell, forced are as with farge quantities of water. Product or runsales that

14 m wher pt to between 7.2 to 7.6. Adjust und maintuin the alkalimity of the pool to between 57 to 100 stile of turne by world t. Chirck the level of unadative chlorine with a test art. Adjust and maintain pool to 1-guillion of SAMYOEJE SUPER SMOCK for each 10,000 gallons of water to yield 5 to 10 ppm avail-SWIMMING pool water disinfection. I us a new poul or spring stan-up, superchlorinate with 's gallon

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to doned will depend upon temperature and minibit of swimmers che once residual and alcoholy of the water trespontity with appropriate test kits. Frequency of water Statistics if posts stoods reprintion a resident of 10 to 15 ppin avail, blo chorine. Test the pH, available ew in 101kH guitaris of water to yacht an a whithe chosine residual between 0.6 to 1.0 pprinby weight To mawdian the pool add minually or by a leeder device 11 oz of SANYGEN SUPER SHOCK for

telaren 14th Jupp ne Grant the several available of home wat raited bit. But not reenter pool until the chlorine residual is for ty 2 days or as to crossing sugered to multe the pool with or gailon to 1 gallon of SANYGEN 531 £365 http://k.t.r.e.w.h.fd/failigari a satawater to yadd 5 to 10 ppm available chlorare by weight

for a state of a state of the s terails wertto daup de ficiti, herbit y in cash of other discharge. Do not offerinate the pool within 24 of the cold of the say strong pool to account at en ader is to be dramed from the pool, chilarate must

Fry a trial deficial kid. Gover providing the restor of deviand heater components for winter by following rest fraid guiltons, while filter is minum provided to rather a 3 ppm available chilomne residual, as determined With I Eth Zithis Profit S - White water is shill clear & clean, epply 3 oz jut SANYGEN SUPER SHOCK manula laters within hors

STR4 IT STR3CK yes that games of active to obtain a free available chitaine concentration of 5 ppm. SPAS, HOT-TUBS, IMMERSION TANKS, ETC : SPAS/HOT-TUBS - Apply 6 of of SANYGEN

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as determined by a suitable chlorine test kit. Adjust and maintain pool water pH to between 7.2 and 7.8. Some oils, totions, tragrances, cleaners, etc. may cause foarning or cloudy water as well as reduce the efficiency of the product.

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To mair fain the water apply 6 oz of SANYGEN SUPER SMOCK per 1000 gallons of water over the surface to maintain a chlorine concentration of 5 ppm

Attur each use, shock freat with 9 oz of SANYGEN SUPER SHOCK per 500 gallons of water to control odor and algae

During extended periods of disuse, add 4 nz of SANYGEN SUPER SHOGX daily for 1000getions of the statement of maintain a 3 ppm chlurine concentration

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Character Spectral and the annex of popyrearies for the set of the set of

ENVIRONMENTAL HAZARDS. This product is toxic to lish. Do not discharge into lakes, streams, purius or public waterways unless in accordance with a NPDES permit. For guidance, contact the regional office of the U.S. Environmental Protection Agency.

PHYSICAL OR CHENICAL HAZARDS

STRONG OXIDIZING AGENT. Mix only with water according to tabel directions. Mixing this product with chumicals (e.g. ammorival acids detergents, etc.) or organic matter (e.g. unine, leces etc.) with release childrine gas which is initiating to eyes, lungs and mucous membranes.

STATEMENT OF PRACTICAL TREATMENT (FIRST AID)

IF CONTACT WITH EYES OCCURS, flush with water for at least 15 minutes. Get prompt medical attention

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IF CONTACT WITH SKIN OCCURS, wash with plenty of soap and water

IF SWALLOWED, drink targe quantities of milk or getatin solution, if these are not available drink targe quantities of water DO NOT give vinegar or other acids DO NOT induce vomiting. Get prompt models that the second s

medical attention

NOTICE: APPLY THIS PRODUCT ONLY AS SPECIFIED ON THIS LABEL Buyer assumes all right and used contrary to directions

MANUFACTUMED BY MIAMI PRODUCTS & CHEMICAL CO. DAYTON, OHIO 45403

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COMPLAINANT EXHIBIT No. 7

1/2 278-43 1.1 SWIMINING POOL WATER DISINFECTION: For a new pool or spring start-up, superchorinate with 1/2 gallon to 1 gallon of product for each 10,000 gallons of water to yield 5 to 10 ppm available chorine by weight. Check the level of available chorine with adjust and maintain pool water the belween 7.2 and 7.8. Adjust and maintain the alkalinity of the pool to between 50 and 100 ppm. DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling. NOTE: This product degrades with age. Use a chlorine test kit and increase dosage, as necessary, to obtain the required level of available chlorine. areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sever. Do not reuse container but place in trash collection. Do not contaminate tood or feed by storage, disposal or clearing of equipment. STORAGE AND DISPOSAL: Store this product in a cool dry area, away from direct surlight and heat to avoid detenoration. In case of spill, flood PHYSICAL OR CHEMICAL HAZARDS: STRONG OXIDIZING AGENTS: Mix only with water according to label directio Mixing this product with chemicale (e.g., emmorile, actiat, detargents, etc.) the gas which is initiating to the and rubber give isted arose as soon as possible. Do not return until strong adors have di ENVIRONMENTAL HAZARDS: This posticide is texts to theh and aq PRECAUTIONARY STATEMENTS 43 5 5 5 5 2 T 20 HAZARDS TO HUMANS AND DOMESTIC ANIMALS ind a get or organic matter (e.g., urina, tacea, etc.) will release this product. Weeh af ayes, lungs and mu STORE CONTAINER IN AN UPPRONT POSITION 1691 0

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10-3-2003

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		FORM APPROVED OMB NO. 2070-0078						
Application for Registration of Pesticide-Producing and Device-Producing Establishments Section 7, Federal Insecticide, Fungicide, and Rodenticide Act, (7 U.S.C. 136e) Note: Read all instructions before completing.								
1. Company Name <u>MIAMI PRODUCTS 4 CHEMICAL CO</u> 2. Company Name (If different from 1)					11. EPA Company Number 278-0H			
Company Vandeuerters Location				00 - 427 - 9378				
Company Headquarters Location					13. Enter Appropriate Ownership code			
4. City		2 - Partnership 3 - Cooperative Association 4 - Corporation 5 - Other						
DAYTON	or County OH	Code 4						
Company Headqual (If identical to al	nters Mailing Address bove, write SAME)	8		14. State or Country of Incorporation				
Address P.O. BOX 42	et or PO Box P.O. BOX 486			15. Date of Incorp (Month, Day,	oration Year)			
S. City DAYTON	9. State or Country	10. Zip Code 4	5401	JANU	JANUARY 16, 1932			
NAME, SITE LOCATIO	N, and MAILING ADDRI	ESS of EACH	NEW PRODUCI	NG ESTABLISHM	ENT			
16. Establishment Name MIAMI PRODUCTS & CHEMICAL CO. (EPA Est. No. (EPA use only) 275.0 202								
17. Establishment Site Address 1260 SCHWERMA	N DR.	18. CHY FAIRBORN			Country	20. Zip Code 4 5 3 2 4		
21. Establishment Malling Address P. O. BOX 4	86 22	22. CHY DAYTON 2			Country	24. Zip Code 4540 j		
26. NAICS Code.		26. D & B No.						
16. Establishment Name		ſ	EPA Est. No. (EPA use only)	001				
17. Establishment Site Address	18	I. City	19. State or	Country	20. Zip Code			
21. Establishment Mailing Address	22	22. City			23. State or Country 24. Zip Code			
25. NAICS Code.			26. D & B No.					
16. Establishment Neme	EPA Est. No.							
17. Establishment Site Addrese	18	. City	19. State or	Country	20. Zip Code			
21. Establishment Mailing Address	22.	L City	23. State or	23. State or Country 24. Zip Code				
25. NAICS Code.				26. D & B No.				
EPA	····			1.4 (¹⁴ - 17)				
USE								
27. NAME of Company ROGER K. KAYSE	- (2. 28. Te Numb	elephone er 937	253-29	Z7 EPA	Received da Postmark da	te Ite		
29. E-mail Address (Optional)	7-253-	USE Signature						
31. TITLE of Company Officer PRESIDEN 7	32. Da (Mont	2. Date Signed (Month, Day, Year) FEB. 23. 2005			ONLY			
33. SIGNATURE of Company Officer Review Date								
EPA Form 3540-8 (Rev. 04-01) Previous edition	Generalia				I	J		

COMPLAINANT EXHIBIT No. 8

