Inert Ingredients in Pesticide Products

Inert Ingredients in Pesticide Products; Policy Statement

OPP-36140; FRL-3190-1

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces certain policies designed to reduce the potential for adverse effects from the use of pesticide products containing toxic inert ingredients. The Agency is encouraging the use of the least toxic inert ingredient available and requiring the development of data necessary to determine the conditions of safe use of products containing toxic inert ingredients. In support of these policies, the Agency has categorized inert ingredients according to toxicity. The Agency will (1) require data and labeling for inert ingredients which have been demonstrated to cause toxic effects; (2) in selected cases pursue hearings to determine whether such inert ingredients should continue to be permitted in pesticide products; (3) require data on inert ingredients which are similar in chemical structure to chemicals with demonstrated toxic properties or which have suggestive, but incomplete data on toxicity; and (4) subject all new inert ingredients, both for food and non-food uses, to a minimal data set and scientific review. The Agency is soliciting comments on these policies.

EFFECTIVE DATE: This policy is effective on April 22, 1987, subject to revision if comments received warrant such revision.

ADDRESSES: Three copies of written comments bearing the document control number [OPP-36140] should be submitted, by mail, to:

Information Services Section,
Program Management and Support Division (TS-757C),
Office of Pesticide Programs,
Environmental Protection Agency,
401 M St. SW.,
Washington, DC 20460.

In person deliver comments to:
Rm. 236, CM #2,
1921 Jefferson Davis Highway,
Arlington, VA.

Information submitted as a comment in response to this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public docket. Information not marked confidential will be included in the public docket without prior notice. The public docket is available for public inspection in Room 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:

Tina Levine,
Hazard Evaluation Division
(TS769C),
Environmental Protection Agency,
401 M St. SW.,
Washington, DC 20460.
(703-557-9307).

Office location and telephone number:
Rm. 788E, CM #2,
1921 Jefferson Davis Highway,
Arlington. VA
(703-557-9307).

SUPPLEMENTARY INFORMATION: EPA is issuing this notice announcing certain policies regarding inert ingredients in pesticide products.

I. Definitions

1. Active ingredient. An ingredient which will prevent, destroy, repel, or mitigate any pest, or will alter the growth or maturation or other behavior of a plant, or cause the leaves or foliage to drop from a plant, or accelerate the drying of plant tissue.

2. Inert ingredient. For purposes of this policy, any intentionally added ingredient in a pesticide product which is notpesticidally active. This definition does not include impurities.

3. Closely similar product. A pesticide product that (1) contains the same active ingredient(s) in substantially the same percentage(s) as a product already registered, (2) is intended for the same use pattern as the already-registered product, and (3) contains no greater percentage of any List 1 or List 2 inert ingredient than the already-registered product.

II. Background and Legal Authority

A. *The Federal Insecticide, Fungicide, and Rodenticide Act*

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), requires that all pesticide products sold or distributed in commerce be registered by the Environmental Protection Agency (EPA or Agency). Prior to the establishment of EPA, the Department of Agriculture (USDA) registered pesticides under FIFRA. Most of the data requirements and regulatory activities under FIFRA have focused on the active ingredient. There are two exceptions to this general policy; (1) A battery of acute toxicity tests on the pesticide formulation, which generally includes both active and inert ingredients, is routinely required for registration of an end-use product; (2) The Agency has imposed certain labeling requirements for hazardous inert ingredients (49 FR 37980, September 26, 1984).

B. Federal Food, Drug and Cosmetic Act

In addition to its mandate under FIFRA, EPA has authority to regulate pesticide products under the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408 of FFDCA authorizes EPA to establish tolerances or safe levels of pesticide residues in raw agricultural commodities; section 409 similarly authorizes EPA to issue food additive regulations for pesticide residues in processed foods. Prior to the establishment of the EPA, the Food and Drug Administration (FDA) had the responsibility for establishing tolerances and food additive regulations for pesticide residues.

The FDA has issued several notices explaining its policy with regard to regulation of inert ingredients in pesticides under the FFDCA. In 1961, FDA published a notice in the **Federal Register** stating that USDA had determined that each component of registered pesticide products, including the inert ingredients, were pesticide chemicals and thus subject to the

requirement of tolerances or exemption under FFDCA (26 FR 10640, November 14, 1961). In 1969, the FDA established a policy regarding data requirements and review procedures for clearance of inert ingredients (34 FR 6041, April 3, 1969). This notice set forth general toxicity data requirements and stated that residue data requirements would depend on the toxicity of the chemical. However, the policy allowed a less formal review process if FDA conclude that the inert ingredient was generally recognized as safe for the stated purpose. Exemptions from the requirement of a tolerance for inert ingredients have generally occurred through the informal request procedure, rather than the formal petition process required for active ingredients. Inert ingredients exempt from the requirement of a tolerance are codified in 40 CFR 180.1001.

There are currently approximately 1,200 inert ingredients in pesticide formulations. About half of these have been cleared for food use under section 408 or 409 of FFDCA. Many of those chemicals had been approved by the FDA for non-pesticidal use as food additives, for example, as flavorings or in packaging, before they began being used in pesticide formulations. These chemicals were generally exempted from the requirement of a tolerance with little systematic review or screening by the EPA. Inert ingredients in products registered only for non-food uses also have received little scientific review.

III. Development of Regulatory Policy for Inert Ingredients

Because of concern that some inert ingredients in pesticide products might cause adverse effects to humans or the environment, the Agency developed a draft strategy for the regulation of inert ingredients, which was reviewed by the FIFRA Scientific Advisory Panel and was made available to the public in Spring 1986. This **Federal Register** notice announces the policy of the Agency regarding inert ingredients in pesticide products and is based on the strategy.

EPA has divided the approximately 1,200 intentionally-added inert ingredients currently contained in pesticide products into four toxicity categories:

1. Inerts of toxicological concern (List 1).
2. Potentially toxic inerts/high priority for testing (List 2).
3. Inerts of unknown toxicity (List 3).
4. Inerts of minimal concem (List 4).

EPA has identified about 50 inert ingredients as being of significant toxicological concern. This list was assembled on the basis of known toxicity of the chemical; no consideration was given to the potential for exposure. The criteria used to place chemicals on List 1 were carcinogenicity, adverse reproductive effects, neurotoxicity or other chronic effects, or developmental toxicity (birth defects). These effects must have been demonstrated in laboratory or human studies and the data subject to peer review. The criteria also included documented ecological effects and the potential for bioaccumulation. These criteria and the list, itself were reviewed by the Scientific Advisory Panel. List 1, inerts of toxicological concern, is as follows:

LIST 1. INERTS OF TOXICOLOGICAL CONCERN

CAS No.	Chemical Name
62-53-3	Aniline
1332-21-4	Asbestos fiber
71-43-2	Benzene
1332-21-9	1,4-Benzenediol
3068-88-0	B-Butyrolacetone
7440-43-0	Cadmium compounds
75-15-0	Carbon disulfide
56-23-5	Carbon tetrachloride
108-90-7	Chlorobenzene
67-66-3	Chloroform
62-73-7	DDVP
106-46-7	p-Dichlorobenzene
117-87-7	Di-ethylhexylphthalate (DEHP)
54-14-7	1,1-Dimethyl hydrazine
540-73-8	1,2-Dimethyl hydrazine
534-52-1	Dinitro-o-cresol
51-26-5	Dinitrophenol
123-91-1	Dioxane
106-89-8	Epichlorohydrin
110-80-5	Ethanol, 2-ethoxy (cellulosive)
111-15-9	Ethanol ethoxy acetate

96-45-7	Ethylene thiourea
107-06-2	Ethylene dichloride
109-86-4	Ethylene glycol monomethyl ether; methyl cellulosive
140-88-5	Ethyl acrylate
77-83-8	Ethyl methyl glycidate
50-00-0	Formaldehyde
70-30-4	Hexachlorophene
110-54-3	n-Hexane
302-01-2	Hydrazine
78-59-1	Isophorone
7439-92-1	Lead Compounds
569-64-2	Malachite Green
1191-80-6	Mercury oleate
591-78-6	Methyl n-butyl ketone
74-87-3	Methyl chloride
75-09-2	Methylene chloride
79-46-9	2-Nitropropane
25154-52-3	Nonylphenol
30525-89-4	Paraformaldehyde
87-86-5	Pentachlorophenol
127-18-4	Perlcoroethylene (PERC)
108-95-2	Phenol
90-43-7	o-Phenylphenol
78-87-5	Propylene dichloride (1,2-dichloropropane)
75-56-9	Propylene oxide
8003-34-5	Pyrethrins and pyrethroids
81-88-9	Rhodamine B
10588-01-9	Sodium dichromate
131-52-2	Sodium pentacholorohenate
62-56-6	Thiourea

26471-62-5	Toluene diisocyanate
79-00-5	1,1,2-Trichloroethane
56-35-9	Tributyl tin oxide
79-01-6	Trichloroethylene
1330-78-5	Tri-orthocresylphosphate (TOCP)
78-30-8	Tri-orthocresylphosphate (TOCP)

EPA has further identified about 60 inert ingredients which the Agency believes are potentially toxic and should be assessed for effects of concern (List 2). Many of these inert ingredients are structurally similar to chemicals known be toxic; some have data suggesting a basis for concem about the toxicity of chemical. Most of the chemicals on List 2 have been designated for testing through the National Toxicology, Program (NTP), the EPA Office of Toxic Substances (OTS) or other regulatory or government bodies. The FIFRA Scientific Advisory Panel has also reviewed this list. Because testing is ongoing for most of chemicals on List 2, it is expected to change periodically. It is the Agency's policy to have all additions, deletions or changes to List 1 or 2 reviewed by the FIFRA Scientific Advisory Panel. List 2 potentially toxic inerts/high priority for testing, is as follows:

LIST 2. POTENTIALLY TOXIC INERTS/HIGH PRIORITY FOR TESTING

CAS No.	Chemical Name
85-68-7	Butyl benzy phthalate
84-74-2	Dibutyl phthalate
84-66-2	Diethyl phthalate
131-11-3	Dimethyl phthalate
117-84-0	Dioctyl phthalate
95-49-6	2-Chlorotoluene
1319-77-3	Cresols
95-48-7	o-Cresol
106-44-5	p-Cresol
108-39-4	m-Cresol

108-94-1	Cyciohexanone
95-50-1	o-Dichlorobenzene
112-34-5	Diethylene glycol monobutyl ether (butyl carbitol)
111-90-0	Diethylene glycol mono ethyl ether (carbitol)
111-77-3	Diethylene glycol mono methyl ether (methyl carbitol)
34590-94-8	Dipropylene glycol monomethyl ether
111-76-2	2-Butoxy-l-ethanol (ethylene glycol mono butyl ether)
5131-86-8	1-Butoxy-2-propanol (1,2-propylene glycollmono butyl ether
124-16-3	1-Butoxyethoxy-2-propanol
107-98-2	1-Methoxy-2-propanol
29387-86-8	Propylene glycol monobutyl ether
25498-49-1	Tripropylene glycol monomethyl ether
577-11-7	Dioctyl sodium sulfosuccinate
141-79-7	Mesityl oxide
106-10-1	Methyl isobutyl ketone
75-52-5	Nitromethane
108-88-3	Toluene
29395-43-1	Tolyl triazole
95-14-7	1,2,3-Benzotriazole
120-32-1	2-Benzyl-4-chlorophenol
7500-3	Chloroethane
88-04-0	p-Chloro-m-xylenol
97-23-4	Dichlorophene
68-12-2	Dimethyl Formanide
100-41-4	Ethyl benzene
149-30-4	Mercaptobenzothiazole
74-83-9	Methyl bromide

75-43-4	Dichloromonofluoromethane
75-45-6	Chlorodifluoromethane
75-37-6	1,1-Difluoroethane
75-68-3	1-Chloro-1,1-difluoroethane
25168-06-3	Isopropyl phenols. Petroleum hydrocarbons
1330-20-7	Xylene
100-02-7	p-Nitrophenol
106-88-7	Butylene oxide
79-24-3	Nitroethane
75-05-8	Acetonitrile
96-48-0	gamma-Butyrolacetone
71-55-6	1,1,1-Trichloroethane
102-71-6	Triethanolamine
111-42-2	Diethanolamine
97-88-1	Butyl methacrylate
80-62-6	Methyl methacrylate. Xylene-range aromatic solvents
95-82-9	Dichloroaniline
95-76-1	Dichloroaniline
626-43-7	Dichloroaniline
554-00-7	Dichloroaniline
608-27-5	Dichloroaniline
608-31-1	Dichloroaniline
101-84-8	Diphenyl ether
76-13-1	Trichlorotrifluoroethane
75-69-4	Trichlorofluoreothane
75-71-8	Dichlorotetrafluoromethane
79-14-2	Dichlorotetrafluoroethane

Inert ingredients were put on List 4 (minimal hazard or risk) if they were generally regarded as innocuous. These included inert ingredients such as cookie crumbs, corn cobs, and substances "generally recognized as safe (GRAS)" by the FDA (21 CFR Part 182). There are approximately 300 inert ingredients in this category.

An inert ingredient was placed on List 3 if there was no basis for listing it on any of the other three lists. There are approximately 800 inert ingredients in this category.

Lists 3 and 4 are not addressed further in this notice since the Agency will be taking no particular regulatory actions with respect to these inert ingredients at this time. Applications for exemptions from the requirement of tolerances for Lists 3 and 4 inert ingredients are discussed in unit VI.

These lists were developed to establish priorities for regulatory activities related to existing inert ingredients. The Agency intends to focus its initial regulatory efforts on the inerts of toxicological concern. For this reason, the current policy notice is most specific with regard to inert ingredients on List 1. As resources permit, EPA will extend its activities to the other inert ingredients.

IV. Inerts of Toxicological Concern (List 1)

In order to reduce the potential for adverse effects to humans or the environment it is the policy of the Agency to encourage the use in pesticide products of the least toxic inert ingredients available and to require development of the information necessary to determine the conditions under which various chemicals may be used safely as inert ingredients in pesticide products. In line with this policy, EPA has developed procedures for dealing with new and existing pesticide registrations containing inerts of toxicological concern. It should be noted that the Agency is currently engaged in a comprehensive review of various chlorinated solvents, several of which are on List 1or List 2. The data gathering described in Section A.3 below will support that effort. As conclusions are made in the Solvents Project, the inerts policy with respect to those substances will be reviewed to see whether adjustments in status would be appropriate. In the meantime, chemicals under review in the Solvents Project are subject to the requirements described below.

A. *Existing Registrations*

1. Substitution. Registrants are encouraged to substitute inert ingredients not included in List 1 or List 2 for inerts of toxicologic concern (List 1) now contained in their products. Reqistrants electing to substitute should submit a new Confidential Statement of Formula as a proposed amendment to the registration. The revised Confidential Statement of Formula should be sent to: Product Manager, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington. DC 20460.

2. Labeling. As an immediate step to inform users and the general public of the presence of an inert of toxicological, concern, EPA is directing registrants of each product containing an inert ingredient on List 1 to submit applications (to the product

manager at the above address) to amend their registrations to add the following statement to the label:

This product contains the toxic inert ingredient *(name of inert).*

T'he wording should be placed in close proximity to the ingredients statement in a type size comparable to other front panel text.

Registrants are required to submit the application not later than October 20, 1987. (At the top of each application, please write in bold letters "INERTS".) No pesticide product containing a List 1 inert ingredient may be released for shipment after October 20, 1988 unless the product bears an amended label which complies with the provisions listed above. EPA may initiate cancellation proceedings under section 6(b)(1) of FIFRA for any product registrations containing a List 1 inert ingredient for which an amended label is not submitted in a timely fashion.

3. Data Requirements. In addition, any registrant who retains an inert of toxicologic concern in his or her product(s) will be subject to data call-in under section 3(c)(2)(B) of FIFRA. The data requirements will take into consideration the chemical's existing data base and the product's use pattern. Because of the demonstrated biological activity of chemicals on List 1. EPA may require as much data as would be required by 40 CFR Part 158 for an active ingredient. For many of these inert ingredients, adequate toxicity data exist but additional exposure data would be required. In addition, data on environmental fate, ecological effects and residue chemistry may be required. The Agency intends to issue data call-in letters for this data beginning in April 1987.

4. Hearings. For certain inert ingredients on List 1, EPA intends to issue Notices of Intent to Hold a Hearing under FIFRA section 6(b)(2). The purpose of these hearings will be to gather and present information on the risks and benefits of these inert ingredients. Based on the information presented during that hearing EPA will determine whether pesticide products containing a particular inert ingredient on List 1 should be cancelled, be subject to additional restrictions, or be allowed to continue their current registrations without change. Hearings conducted under FIFRA section 6(b)(2) are formal adjudicatory proceedings conducted according to the procedures in 40 CFR Part 164. Evidence is presented under oath by witnesses, who are subject to cross-examination. EPA has the burden of proceeding, but the ultimate burden of proof rests on registrants. Decisions are based only on evidence in the hearing record. The presiding Administration Law Judge makes an Initial Decision which may be appealed to the Administrator who makes the Final Decision.

EPA expects to issue the first Notice of Intent to Hold a Hearing concerning an inert ingredient on List 1 in 1987. Subsequent notices may cover several List 1 inert ingredients with similar functions in pesticide formulations, e.g. solvents.

5. Reclassifying Inert Ingredients As Active Ingredients. The Agency has also identified several inerts of toxicological concern which are present in pesticide formulations to act against some pest, although not necessarily the pest targeted by the formulation. For example, an ingredient may be added to a rodent bait to repel flies. Although these ingredients have traditionally been designated as inert ingredients, EPA believes that they are actually active ingredients. These inert ingredients are formaldehyde, paraformaldehyde, hexachlorophene, 2,2-dichloro vinyl dimethyl phosphate, and the pyrethins/pyrethoids. EPA recently indicated its intent to reclassify formaldehyde and paraformaldehyde as active ingredients when used in pesticide products to prevent microbial damage to such products (52 FR 321, January 5, 1987). EPA intends to similarly reclassify the other inert ingredients that prevent damage to pesticide formulations by pests as active ingredients in those formulations. This will simplify the process of obtaining data under FIFRA section 3(c)(2)(B).

6. *Revocation of Exemptions from Tolerance.* Any pesticide chemical used on food must have a tolerance or an exemption from the needfor tolerance. If the Agency determines that an inert of toxicological concern is no longer used in any food-use pesticide product, the exemption(s) from the need for a tolerance will be revoked for that inert ingredient. In addition, there may be circumstances in which EPA willreplace existing exemptions with finite tolerances. Such action will be taken when the data gathered through the data call-in activities on inertsof toxicological concern enable the Agency to establish a finite tolerance**.**

B. New Registrations

In general, no new product that contains an inert of toxicological concern will be registered unless the product is closely similar to an existing product, as defined above. In limited circumstances, other products may be registered if review indicates that the risk of unreasonable adverse effects to humans or on the environment, will be decreased by such a registration. As specified above, the label of any product containing such an inert ingredient will be required to indicate the presence of the inert ingredient. In addition, the product will be registered conditionally, subject to any data requirements that the Agency imposes on registrants of similar products.

V. Potentially Toxic Inerts/High Priority for Testing

The Agency's goal is to collect enough information on each inert ingredient on List 2 to determine whether further actions such as those for inerts on List 1 are necessary. In

order to make this determination, the Agency is monitoring ongoing testing and gathering existing information on the potential adverse effects of these substances and will require additional testing from industry if it is needed.

A. Existing Registrations

EPA does not plan to issue any specific requirements in the near future for inert ingredients on List 2. If an inert ingredient is moved from List 2 to List 1, as new data or information becomes available, it will become subject to the requirements outlined in Section IV of this notice.

B. New Registrations

Closely similar products containing List 2 inert ingredients will continue to be registered. Applications for registration of other products (e.g., new uses) containing inert ingredients that are on List 2 will be reviewed on a case-by-case basis. The Agency will consider the current weight-of-evidence with respect to the hazards posed as well as the potential for increased exposure when deciding whether the product meets the standard for registration.

VI. Inert Ingredients and New Food-Uses of Existing Inerts

Any inert ingredient proposed for use in a pesticide product is considered to be a "new" inert ingredient if it is not currently identified as present in some approved pesticide formulation or has never been in a previously registered product. The minimal data generally required to evaluate the risks posed by the presence of a new inert ingredient in a pesticide product is a subset of the kinds of data typically required for active ingredients under 40 CFR Part 158. A description of the data required and guideline number as listed in 40 CFR Part 158 follows:

DATA REQUIRED TO EVALUATE RISKS POSED BY INERT INGREDIENTS IN PESTICIDE PRODUCTS

	Guideline Ref. Number 40 CFR Part 158
1. KIND OF DATA REQUIRED:	
Residue Chemistry:	
Description of the pesticide type of pesticide formulation(s) in which the inert will be used	

and the maximum percent by weight it can occupy in any formulation.	
Description regarding the range of use patterns and range of concentrations of the inert material [1]	171-3

2. KIND OF DATA REQUIRED:

Product Chemistry:

Description of the chemical or chemical mixture including structual formula(e)	61-1
Chemical Abstracts Services (CAS) Registry Number and file	61-1
Any technical bulletins available on the inert:	
Purpose of the inert in pesticide formulation (i.e., solvent, emulsifier, etc.)	61-1
Discussion of possible toxic contaminants such as nitrosamines, polynuclear aromatics or dioxins	61-3
Batch analyses [2]	62-1
Density/specific gravity	63-7
Solubility	63-8
Vapor Pressure	63-9
Dissociation Constant	63-10
Octanol/Water Partition Coefficient	63-11
pH	63-12

Toxicology:

90-day feeding study: rodent and dog [3]	82-1
Subchronic Dermal toxicity [4]	82-2, 82-3
Teratology study: rodent	83-3
Gene mutation test	84-2
Structural chromosomal aberration test	84-2
Other genotoxic effects	84-4

3. KIND OF DATA REQUIRED

Ecotoxicology: [5]

Acute 96-hr fish LC50 (preferably in rainbow trout or bluegill)	72-1
48-hr LC50 or EC50 in daphnia	72-2
Avain oral LD50 (preferable in mallard or bobwhite)	71-1
8-day avian dietary (preferable in mallard or bobwhite)	71-2

Environmental Fate: [5]

Hydrolysis	161-1
Aerobic soil metabolism	161-1
Photodegredation in water	161-2
Photodegredation in soil	161-3
Koc or Kd	163-1

[1] For use on food crops, include whether preharvest and/or post-harvest applications, or use on livestock, and use any restrictions.

[2] Batch analysis would be required only if there are possible contaminants of concern or if a mixture of variable composition is involved.

[3] If the inert is used in a food-use product, two subchronic feeding studies will be required.

[4] This study may be substituted for the 90-day feeding studies if only non-food use is proposed. The duration of the subchronic dermal study will depend on the potential duration and frequency of human exposure.

[5] Ecotoxicology and environmental fate testing are required only for formulations used outdoors.

In certain circumstances, EPA may waive some or all of these data requirements, for example, if the applicant can show that the proposed new use pattern of the inert ingredient will result in little or virtually no exposure. Data or use information should address dietary, groundwater or applicator exposure, as appropriate. In gathering the data to be submitted to the Agency, the applicant should contact manufacturers trade associations, etc., who may be able to assist in identifying appropriate data. As a minimum, applicants whose formulations contain new food-use inert ingredients should contact the FDA to obtain data and information on inert ingredients that may have approved food additive uses.

In addition to new inert ingredients, the data requirements and review process described above will be used to evaluate requests for additional exemptions from tolerances and changes in exemptions from tolerances of inerts already cleared for food-use and for exemptions from tolerances for existing inert ingredients not presently used on foods. The requirements outlined constitute our "base set" of data needs. If these studies indicate potential human health concerns or ecotoxicity or potential groundwater contamination, further testing may be required to fully assess the risks and define acceptable uses.

VII. Proprietary Inert Ingredients or Mixtures

In the case of some products, the registrant is not aware of the identity of all of the inert ingredients. These products contain a substance (usually a combination of several inert ingredients) which is designed to perform a particular function in pesticide products (e.g., to act as a solvent or emulsifier) but which is sold to pesticide registrants under a trade name without disclosure of the substance's constituents. The seller of such a substance typically will claim that the identity of the constituents in a trade secret. Many of these "proprietary inerts" are marketed in this manner today. EPA has allowed pesticide products containing such substances to be registered if the applicant for registration first arranged to have the supplier of the proprietary inert substance disclose its formula to EPA. This practice poses problems in administering the data call-in and labeling requirements contemplated by this Notice. For instance, EPA may know that a proprietary inert substance contains a List 1 inert ingredient, but may be unable to disclose that fact to the registrants of the products that contain the proprietary substance. EPA obviously cannot require these registrants to list the inert ingredient on their labels, or subject them to a data requirement, until the confidentiality problem is overcome. The approaches set forth below address this problem.

A. Existing Registration

If a product with an existing registration contains an inert of toxicological concern comprising part of a proprietary inert ingredient or mixture. The Agency will request the formulator of the ingredient or mixture to divulge the presence and identity of the inert of toxicological concern to the registrant so that the registrant can label the product properly. If the producer of the proprietary ingredient or mixture refuses to divulge this information, the Agency will require the formulator to justify the claim of confidential business information under 40 CFR Part 2. If EPA reviews the claim and determines that it is without merit, EPA will so inform the formulator of the ingredient or mixture. Thereafter, following the appropriate procedures in EPA regulations, EPA may inform registrants that the proprietary inert ingredient or mixture contains a specific ingredient. If EPA does not decide to disallow a CBI claim, EPA may none-the-less require, FIFRA under section 3(c)(2)(B), that the registrant provide EPA with information showing that the registrant knows the composition of the proprietary inert ingredient or mixture. In either case, once EPA has determined that a registrant is aware that his product contains an inert of toxicological concern which is present in a proprietary inert ingredient or mixture used to formulate the product, EPA will inform the registrant of the regulatory actions being initiated because of the presence of that inert ingredient.

B. Applications for New Registrations

If a registrant submits an application for a new use or identical or a substantially similar use containing an inert of toxicological concern as part of a proprietary inert ingredient or mixture, the Agency will notify the registrant that the product cannot be registered based on the inert ingredients which are contained in the formulation. It will

be the responsibility of the registrant to contact the formulator/supplier of *any* proprietary ingredient or mixtures used in the pesticide formulation and determine the identity of the inert(s) of toxicological concern present in the pesticide formulation.

C . Registrant's Ongoing Responsibility for the Composition of the Pesticide Products

Units VII.A. and VII.B. discuss the procedures the Agency will employ to ensure that a registrant is aware that his product contains an inert of toxicological concern as part of a proprietary inert ingredient or mixture. With the exception of knowing about the presence of inerts of toxicological concern, the Agency does not at this time plan to require that an applicant know or find out the composition of a proprietary inert ingredient or mixture order to obtain registration. An applicant is, however, required to ensure that the Agency is informed of its composition by its producer.

In addition, the Agency does hold a registrant responsible for the certified limits of each inert ingredient in his product, including those that are present as part of a proprietary inert ingredient or mixture. An applicant who does not know the composition of an inert ingredient or mixture, and cannot persuade his supplier or producer to disclose it, may certify to an upper and lower limit of the ingredient or mixture as introduced into his product. In this case, the fact that the applicant uses a proprietary inert ingredient or mixture whose composition is not known to him does not remove his responsibility for maintaining the composition of each of those inert ingredients within it's certified limits and assuring that the composition of the proprietary inert ingredient(s) or mixtures(s) he uses will not change over time. EPA believes that contractual agreement between formulator and supplier is the best way to ensure that the formulator can rely on the composition of the material received short of having direct knowledge of its composition.

Dated: April 13, 1987
J.A.Moore,
Assistant Administrator for Pesticides and Toxic Substances
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