United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

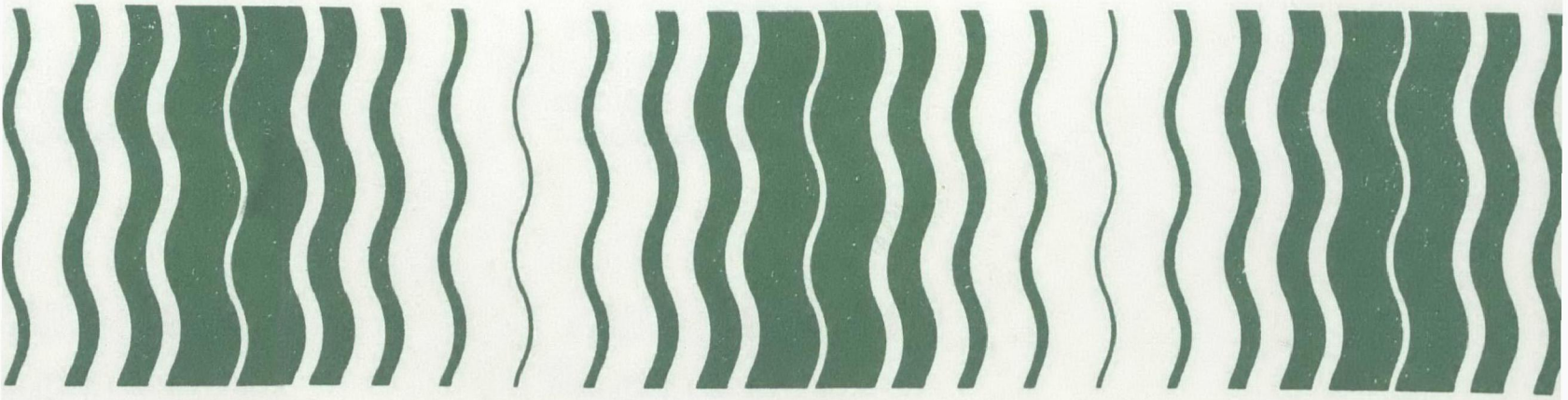
August 1981

Pesticides

EPA

5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide (Carboxin)

Pesticide Registration Standard



CARBOXIN

Pesticide Registration Standard

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I. HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. ORGANIZATION OF THE STANDARD

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. PURPOSE OF THE STANDARD

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> "(1) its composition is such as to warrant the proposed claims for it;
>
> (2) its labeling and other material required to be submitted comply with the requirements of this Act;
>
> (3) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (4) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of

pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use the pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general

use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

C. REQUIREMENT TO REREGISTER UNDER THE STANDARD

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "PRODUCT SPECIFIC" DATA AND "GENERIC" DATA

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific, i.e. data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. Generic data that pertains to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products are also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed guidelines, 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed guidelines,43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be

required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. DATA COMPENSATION REQUIREMENTS UNDER FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain an existing registration;

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

5. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be

the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. OBTAINING DATA TO FILL "DATA GAPS"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product,

but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

G. AMENDMENTS TO THE STANDARD

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities.

Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

II. REGULATORY POSITION AND RATIONALE

A. Introduction
B. Description of Chemical
C. Regulatory Position
D. Regulatory Rationale
E. Criteria for Registration Under the Standard
F. Acceptable Ranges and Limits
G. Required Labeling
H. Tolerance Reassessment

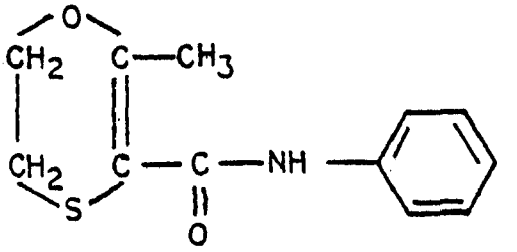
A. INTRODUCTION

This chapter presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing carboxin as the sole active ingredient. After briefly describing carboxin, this chapter presents the regulatory position and rationale, and the criteria for registration of products containing this chemical. These include labeling considerations, and tolerance reassessment. A summary of data requirements is contained in Chapter III. Data supporting this regulatory position are discussed in each of the disciplinary chapters, IV through VIII. Also considered in this Standard are Special Local Need (SLN) registrations which are issued by a State in accordance with FIFRA section 24(c). Valid State registrations will be subject to reregistration under the EPA Registration Standard System, in the same manner as registration issued under section 3 of FIFRA.

B. DESCRIPTION OF CHEMICAL

Carboxin [5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide] is a systemic fungicide registered for use as a seed treatment to protect barley, corn, wheat, oats, cotton, and peanuts; and registered for SLN use only in the states of Alabama, Georgia, North Carolina, Oklahoma, South Carolina, and Texas as a combined foliar and soil application on peanut plants to control Southern blight.

The structural formula is:



Uniroyal, Inc. is the principal producer and registrant. Carboxin (technical material) is formulated into a formulation intermediate, a wettable powder/dust, a dust, two ready-to-use liquids (flowable), two soluble concentrate liquids; and also a granular formulation and flowable concentrate for SLN use only.

Carboxin is unusual because it is systemically toxic to phytopathogenic Basidiomycetes. It is less toxic to phytopathogenic fungi of other classes, therefore, it is commonly applied in combination with thiram or

captan, or applied to seed previously treated with other fungicides to broaden the spectrum of diseases controlled. Any combination (i.e. mixture) of carboxin with other pesticides will not be considered in this Standard at this time.

C. REGULATORY POSITION

Based on a review of the available scientific data and other relevant information on carboxin, the Agency has made the following determinations:

1. Pesticide products containing this sole active ingredient may be registered, subject to the terms and conditions specified in this Standard.

2. None of the risk criteria for determining unreasonable effects has been met or exceeded for this active ingredient.

3. The registrant must develop or agree to develop additional data, specified in Chapter III, to maintain the existing registration or to permit new registrations.

4. Tolerances for registered uses on barley, wheat, oats, corn, cotton, and peanuts are supported by the residue and toxicology data submitted for seed treatment uses. Tolerances are not supported for the combined foliar and soil application on peanuts (SLN use).

D. REGULATORY RATIONALE

Exposure via drift of the chemical is possible because the granular formulation is broadcast aerially for the combined foliar and soil treatment to peanut plants. Although the flowable concentrate formulation is applied by overhead irrigation or sprayed as a ground application, exposure is expected to be minimal due to the dilutions used and the use directions that state that the spray is to be directed at the crown of the plant, thereby minimizing possible drift in this use pattern.

For the predominant use pattern, dermal exposure from handling treated seed is expected to be low because most seeds are mechanically planted.

Potential exposure to wildlife exists through the ingestion of treated seeds and granules. Mechanically planted seeds may be left uncovered or partially uncovered at the end of rows, and therefore wildlife, especially birds, could ingest treated seeds.

Because there are no registered public health related uses, the Agency has waived the need for efficacy data to support the uses of carboxin.

The Agency has concluded that it should continue the registration for this chemical for the following reasons:

1. No significant adverse effects data of regulatory concern have been uncovered in the review of the studies which have been received, either in studies sufficient to meet data requirements or in those which fail to meet data requirements but which provide some level of qualitative information.

2. No significant potential risk associated with the use of carboxin is indicated from the accident data as reported on this chemical.

3. In accordance with FIFRA, the Agency's policy is not to cancel or to withhold registration merely for the lack of data. (See sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, publication of the Standard provides a mechanism for identifying data needs, and registration under the Standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of this chemical.

E. CRITERIA FOR REGISTRATION UNDER THE STANDARD

To be subject to this Standard, products must meet the following conditions:

- contain carboxin as the sole active ingredient; and

- bear required labeling; and

- conform to the acute toxicity limits, product composition and use pattern requirements stated in Section F, below.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in this Standard including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D). As discussed in chapter I, applicants for registration under this Standard must contact the Registration Division for specific instructions, including updated information contained in the guidance package on data requirements, and companies whose data must be cited and to whom compensation must be offered.

F. ACCEPTABLE RANGES AND LIMITS

1. Manufacturing-Use Products

a. Product Composition Standard

Currently the Agency has minimal information that indicates ranges and limits for the product composition of manufacturing-use products

containing carboxin. To be covered under this Standard, registrants of manufacturing-use products containing carboxin must certify ranges and limits for both active and inert ingredients, and impurities.

b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use products containing carboxin regardless of the toxicity category, provided that the labeling of such products bears appropriate precautionary statements.

c. Use Patterns and Application Methods

To be registered under this standard, manufacturing-use products containing carboxin must be labeled to allow for formulation only into end-use products which are intended for use as:

1) application to seeds of barley, corn, wheat, oats, cotton, or peanuts, and/or,
2) combined foliar and soil application to peanuts.

2. End-Use Products

a. Product Composition Standard

Currently the Agency has minimal information that indicates ranges and limits for the product composition of end-use products containing carboxin. To be covered under this Standard, registrants of end-use products containing carboxin must certify ranges and limits for both active and inert ingredients.

b. Acute Toxicity Limits

The Agency will consider registration of end-use products containing carboxin for treating seeds and combined foliar and soil application under a general-use classification, provided that they bear appropriate precautionary labeling.

c. Use Pattern and Application Method Limits

To be registered under this standard, end-use products containing carboxin must be labeled as a systemic fungicide for one or more of the following uses: application to seeds of barley, oats, wheat, corn, cotton, and peanuts. The data on combined foliar and soil application on peanuts do not adequately support registration for these uses under section 3 of FIFRA.

The full range of acceptable use patterns, maximum application rates, preharvest intervals, application methods, and other conditions are specified in Table 1.

TABLE 1
Dosage Rates and Use Limitations

SITE	MAXIMUM DOSAGE	USE LIMITATIONS
Barley (grain crop)	2.25 oz. a.i./100 lb. seed	Seed treatment only
Barley (seed crop)	3.00 oz. a.i./100 lb. seed	Seed treatment only
Cotton	6.00 oz. a.i./100 lb. seed	Seed treatment only
Peanuts	4.50 oz. a.i./100 lb. seed	Seed treatment only
Oats	1.12 oz. a.i./100 lb. seed	Seed treatment only
Wheat (grain crop)	2.25 oz. a.i./100 lb. seed	Seed treatment only
Wheat (seed crop)	3.00 oz. a.i./100 lb. seed	Seed treatment only
Peanuts	1.0 lb. a.i./acre	Granular combined foliar and soil application use only.[a] Preharvest interval - 20 days.[b]
Peanuts	16 oz. a.i./acre	Ground spray only.[a] Preharvest interval - 60 days.[c]
Peanuts	10.9 oz.a.i./acre	Overhead irrigation only.[a] Preharvest interval - 60 days.[c]

a/ Combined foliar and soil application to peanuts can be registered under this Standard provided (1) adequate residue data are developed to show that the present tolerance is adequate to cover the proposed use, or (2) 40 CFR 180.301 is revised to accomodate the residues occuring from the use on peanuts, peanut hulls, and peanut hay.

b/ Currently registered only as a Special Local Need (24(c)) registration in Georgia, North Carolina, Oklahoma, and Texas.

c/ Currently registered only as a SLN registration in Alabama, Georgia, North Carolina, Oklahoma, South Carolina, and Texas.

G. REQUIRED LABELING

All manufacturing-use and end-use products containing carboxin must bear labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains specific information regarding label requirements. In addition, the following specific labeling requirements may apply:

1. Manufacturing-Use Products

a. Use Pattern Statements

All manufacturing-use products containing carboxin must list on the label the intended end-uses of formulated products produced from manufacturing-use products. These statements are necessary to identify the applicability of certain of the data requirements which are necessary only in support of manufacturing-use products intended for formulation into products labeled for combined foliar and soil application. These products must bear one or both of the following statements on the label:

1. "For formulation into products intended for fungicide treatment of seeds.

2. "For formulation into products intended for combined foliar and soil fungicide application."

b. Precautionary Statements

There are no unique precautionary statements which must appear on labeling of manufacturing-use products containing carboxin. The guidance package provides an updated list of all required precautionary statements typical for this type of product. The Agency may, after review of the data required under this Standard, impose additional label requirements.

2. End-Use Products

a. Precautionary Statements

For all seed treatment uses:

"Do not use treated seed for food, feed, or oil puposes."

For cotton:

"Do not graze or feed livestock on hay grown from treated seed."

For peanuts (combined foliar and soil application only):

"Do not hog down treated peanut fields prior to harvest." or

"Do not graze or feed livestock on treated areas."

For barley, corn, oats, and wheat:

"Do not graze or feed livestock on treated areas for six weeks after planting."

The guidance package provides an updated list of all required precautionary statements typical for this type of product. The Agency may, after review of the data required under this Standard, impose additional label requirements.

H. TOLERANCE REASSESSMENT

Tolerances reflecting seed treatment use have been established for combined residues of the fungicide carboxin and its metabolite 5,6-dihydro-3-carboxanilide-2-methyl-1,4-oxathiin-4-oxide (calculated as carboxin) in or on raw agricultural commodities as follows: 0.5 ppm in or on forages of barley, oats and wheat; 0.2 ppm (negligible residue) in or on cottonseed, peanuts, peanut hay and peanut hulls; 0.2 ppm in or on barley, (grain and straw), corn (grain, fodder and forage), fresh corn including sweet corn (kernels plus cob with husk removed), oats (seed and straw), rice and rice straw, sorghum (grain, fodder and forage), soybeans, and wheat (grain and straw): 0.1 ppm in meat, fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep; 0.01 ppm in eggs; and 0.01 ppm in milk (40 CFR 180.301). Codex Maximum Residue Limits (MRL) have not been established for carboxin. There are no Canadian or Mexican tolerances.

Data summarized in this Standard support the established tolerances on corn, cottonseed, peanuts, sorghum, barley, oats, wheat, meat and meat by-products, and milk. Established tolerances on soybeans and rice are supported by residue data obtained with multiple-active ingredient formulations. The establishment of tolerances in poultry, meat, meat by-products and fat, and eggs are based on the conclusion that it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues. In part, this conclusion is supported by the absence of observed bioaccumulation in a ruminant feeding study.

According to available data, the seed treatment use of carboxin falls under category (2) of 40 CFR 180.6(a), i.e. while it is not possible to to establish with certainty whether finite residues in meat, milk, poultry, and eggs will result from the feeding of commodities grown from carboxin-treated seed, there is a reasonable expectation of finite residues based on the feeding of exaggerated levels of carboxin.

Carboxin tolerances on crops are based on residue data obtained with a gas chromatographic method that does not determine insoluble anilide complexes. However, residues in growing crops, analyzed by a colorimetric method that determines both soluble and insoluble residues, decline at a rate such that residues in mature crops would not be expected to exceed tolerance levels.

In calculating the theoretical maximum residue contribution (TMRC), the Agency assumes that the chemical is applied to all commodities on which its use is registered, that each commodity contains the maximum level allowed by the tolerance, and average 60 kg. adult eating patterns result in 100 percent of carboxin-treated foods in the adult diet of 1.5 kg./day. The TMRC of carboxin to the human diet is calculated to be 0.071 mg/day. The Agency has calculated an acceptable daily intake (ADI) value of 0.4 milligrams of carboxin per kilogram of body weight per day. This value is based on a "no-observed-effect" level (NOEL) of 200 ppm established in a two year rat feeding study, and the incorporation of a 100 fold safety factor in translating the data from animal to man.

Based on the TMRC of carboxin to the diet and the fact that the available data do not indicate an unreasonable effect in test animals, the established tolerances (for seed treatment only) are considered adequate to protect public health.

It must be emphasized that the established tolerances provide only for the seed treatment use of carboxin. Combined foliar and soil application of carboxin to peanuts which is registered in six states under Section 24(c) of FIFRA, may result in higher residues than those from seed treatment, thereby necessitating a higher tolerance. Additional data to evaluate this SLN use are required.

III. SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

Applicants for registration of manufacturing-use and end-use carboxin products must cite or submit the information identified as required in the tables in this chapter. The tables applicable to end-use products indicate whether the product to be tested is the technical grade or formulation. Data generated on one formulation may be used to satisfy the data requirement for a substantially similar formulation. Information on which product specific data requirements are already met is available in the guidance package.

Before each requirement is listed the section of the Proposed Guidelines which describes the type of data and when the data are required to be submitted [43 FR, 29696 of July 10, 1978; and 43 FR, 37336 of August 22, 1978]. Justification for why the test is required is provided in the Guidelines. A discussion of why data additional to those already submitted are necessary, or why data normally required are not necessary for this chemical, are explained in footnotes to the tables. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing are indicated.

CARBOXIN

A-1. Generic Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.62-7(b)	Hydrolysis	1/	no	-	yes, 14 months
163.62-7(c)	Photodegradation	1/	partial	00003088 2/	yes, 14 months
163.62-8(b)	Aerobic Soil Metabolism	1/	partially 3/	00005540 00003225 05002176 00003041 00002935 05004996	yes, 14 months
163.62-8(c)	Anaerobic Soil Metabolism	1/	partially 4/	00003226	yes, 14 months
163.62-8(f)	Microbial Metabolism:				
	(2) Effects of Microbes on Pesticides	-	partially	00005540 05004129 05005110 05006789 05003218	reserved 5/
	(3) Effects of Pesticides on Microbes	-	partially	00005540 05002757 05003947 05003657 05003852	reserved 5/

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ Radiolabeled analytical grade or non radiolabeled technical material.

2/ This study is useful and fills part of the requirements i.e., it provided information on rate of photodegradation under natural and artificial lights. However it failed to identify the photo products. Thus further data are required. A study of photolysis on soil is also required.

3/ Data are required on aerobic soil metabolism of carboxin sulfoxide (preferably in silt loam, loamy sand or sandy soils). The data are insufficient to evaluate carboxin sulfoxide persistence in aerobic soil.

4/ Additional data are required to include 2 more soil types (preferably loam and silt loam soils).

5/ Requirements for the submission of these data are currently being reserved pending development of protocols by the Agency.

CARBOXIN

A-2. Generic Data Requirements: Environmental Fate (See Chapter V)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.62-8(g)	Activated Sludge Metabolism	-	-	-	reserved[1]
163.62-9(b)	Leaching	2/		00003227 00003114 00003229	no[3]
163.62-9(d)	Adsorption/Desorption	2/	all	00005541 05003915	no
163.62-10(b)	Terrestrial Field Dissipation:				
	(1) Field & Vegetable Crops	Representative Formulation	partially[4]	00003087	yes, 14 months
163.62-11(b)	Accumulation in Rotational Crops	5/	partially[6]	00003114 00003224	yes, 14 months
163.62-11(d)	Fish Accumulation	2/	all	00005544 00005545	no
163.62-13	Disposal & Storage	-	-	-	reserved[1]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ Requirements for the submission of these data are currently being reserved pending developement of protocols by the Agency.

2/ Radiolabeled analytical grade or non radiolabeled technical material

3/ Data requirements have been met by data submitted on adsorption/desorption.

4/ Dissipation and mobility rates for carboxin formulations under actual use conditions are required.

5/ Radiolabeled analytical grade, and if radioactivity is found in the crops, followed with a field study using a typical representative formulation product.

6/ The available data satisfy the lab data requirements, however a field study is needed to determine if residues will be taken up by rotational crops.

CARBOXIN

A-1. Generic Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.81-1	Acute Oral Toxicity	Technical Grade of Active Ingredient	all	00003065	no
163.81-2	Acute Dermal Toxicity	Technical Grade of Active Ingredient	all	00003066	no
163.81-3	Acute Inhalation Toxicity	Technical Grade of Active Ingredient	partially[1/]	00003116	yes, 14 months
163.81-4	Primary Eye Irritation	Technical Grade of Active Ingredient	no	-	yes, 14 months
163.81-5	Primary Skin Irritation	Technical Grade of Active Ingredient	all	0003119	no
163.81-6	Dermal Sensitization	Technical Grade of Active Ingredient	no	-	yes, 14 months
163.82-1	Subchronic 21-Day Oral	Technical Grade of Active Ingredient	all	00003063 00003030	no
163.82-2	Subchronic 21-Day Dermal Toxicity	Technical Grade of Active Ingredient	all	00003216	no
163.82-4	Subchronic Inhalation Toxicity	Technical Grade of Active Ingredient	no	-	reserved[2/]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ Since the study gave neither the particle size nor the actual concentration of carboxin in the inhalation chamber, further testing is required.

2/ Will depend on results of an acute inhalation test for technical carboxin.

A-2. Generic Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.83-1	Chronic Feeding	Technical Grade of Active Ingredient	all	00003031 00003152	no
163.83-2	Oncogenicity	Technical Grade of Active Ingredient	partially	00003031 00003152	yes[1/], 38 months
163.83-3	Teratogenicity	Technical Grade of Active Ingredient	partially	00003120	yes[2/], 24 months
163.83-4	Reproduction	Technical Grade of Active Ingredient	all	00003032	no
163.84-2 through -4	Mutagenicity	Technical Grade of Active Ingredient	partially	00003118	yes[3/], 24 months
163.85-1	Metabolism (Identification of Metabolites)	Technical Grade of Active Ingredient	all	00002945 00002943 00002944	no

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ An eighteen-month mouse oncogenicity study is needed to meet this requirement.

2/ A teratogenicity test is needed on a second mammalian species, i.e. in addition to the test on rats.

3/ Test choices within these categories must be accompanied with rationale.

(1) At least 1 more test for detecting gene mutations from among these types:
- . Insects e.g. sex-linked recessive lethal test.
- . Mammalian somatic cells in culture with and without metabolic activation.
- . Mouse specific locus test.

(2) At least 3 test for detecting chromosomal aberrations (see 163.84-1(b)(2)(ii).

(3) At least 2 tests for detecting primary DNA damage (see 163.84-1(b)(2)(iii)).

A-1. Generic Data Requirements: Residue Chemistry (See Chapter VII)

Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
Metabolism in Plants	Radiolabeled Active Ingredient	partially[1/]	05001172 05001304 05001302 05002793 05006363 05013368 05002886 05003664 05003673 05003663 05002177 00003044 00002941	yes[1/], 14 months
Metabolism in Animals	Radiolabeled Active Ingredient	partially		yes[2/]
Analytical Methods	Technical Grade of Active Ingredient	partially	05002737[3/] 00003058 00003335[3/] 00002919 00003054 00002905 00002940 00002857[5/] 00025467 00025468 00025483	yes[4/]

1/ There are sufficient data for seed treatment use; however, only partial data have been submitted for the combined foliar and soil use on peanuts, new data will be necessary.

2/ Additional studies to determine the adequacy of milk and meat tolerances may be necessary depending on the outcome of the peanut plant metabolism and residue studies.

3/ Suitable for obtaining residue data, but not suitable for tolerance enforcement.

4/ Additional studies may be necessary if new metabolites are identified by the metabolism studies.

5/ This method is acceptable for tolerance enforcement on meat, milk, and eggs. This same method may be acceptable for enforcement of tolerances on crops if supported by validation data that showed detection of insoluble anilide complexes.

A-2. Generic Data Requirements: Residue Chemistry (See Chapter VII)

Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
Residue Data: Crops -			00003335 05002737	
Corn	Technical Grade of Active Ingredient	all	00005852 00003356 00025483	no
Cottonseed	Technical Grade of Active Ingredient	all	00003129 00003185 00025468	no
Peanuts	Technical Grade of Active Ingredient	partially[1/]	00003045 00025468 00002905 00002903 00003300	reserved[2/]
Wheat	Technical Grade of Active Ingredient	all	00003219 00003158 00003045 00003218 00002961	no
Barley	Technical Grade of Active Ingredient	all	00003158 00025468 00003221	no
Oats	Technical Grade of Active Ingredient	all	00025468 00003220 00003158	no
Sorghum	Technical Grade of Active Ingredient	all	00003045 00003054 00025468	no

1/ Only partial data have been submitted for the combined foliar and soil use on peanuts, new data will be necessary.
2/ Studies may be necessary depending on the outcome of peanut plant metabolism and residue studies.

A-3. Generic Data Requirements: Residue Chemistry (See Chapter VII)

Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
Residue Data: Processed Crops -				
Cotton seed	Technical Grade of Active Ingredient	all		no
oil			00002938	
meal			00002938	
Peanuts	Technical Grade of Active Ingredient	partially		reserved[1/], 14 months
meal			00003300	
oil			00003300	
Residue Data:				
milk	Technical Grade of Active Ingredient	partially[1/]	00002945	reserved[1/], 14 months
meat	Technical Grade of Active Ingredient	partially[1/]	00002945	reserved[1/], 14 months
poultry and eggs	Technical Grade of Active Ingredient	no[1/]		reserved[1/], 14 months
Storage Stability	Technical Grade of Active Ingredient	yes	00025466 GS001201	no

1/ These tests may be required pending the outcome of the metabolism and residue studies on peanuts.

A. Generic Data Requirements: Ecological Effects (See Chapter VIII)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.71-1	Avian Single-Dose Oral LD_{50}	Technical Grade of Active Ingredient	no	-	yes, 14 months
163.71-2	Avian Dietary LC_{50}	Technical Grade of Active Ingredient	partial 1/	00003139	yes, 14 months
163.72-1	Fish Acute LC_{50}	Technical Grade of Active Ingredient	no	-	yes, 14 months
163.72-2	Acute Toxicity to Aquatic Invertebrates	Technical Grade of Active Ingredient	no	-	yes, 14 months
163.122-1	Seed Germination	Technical Grade of Active Ingredient	no	-	yes 2/, 24 months
163.122-1	Vegetative Vigor	Technical Grade of Active Ingredient	no	3/	yes 2/, 24 months
163.122-2	Effects on Algae	Technical Grade of Active Ingredient	no	3/	yes 2/, 24 months
163.122-2	Effects on Aquatic Macrophytes	Technical Grade of Active Ingredient	no	-	yes 2/, 24 months

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ Data are required on the avian dietary LD_{50} for an upland game bird. The requirement has been fulfilled for the mallard duck.

2/ These data are required unless the manufacturing-use product is labeled to exclude manufacturing into products intended for combined foliar and soil application to peanuts.

3/ The Agency has evaluated a few studies, but they are insufficient to fulfill the requirements.

B. Product Specific Manufacturing-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-3	Product Identity & Disclosure of Ingredients	Each Product	yes	1/	no
163.61-4	Description of Manufacturing Process	Each Product	partially 2/	-	yes 3/
163.61-5	Discussion on Formation of Unintentional Ingredients	Each Product	no	-	yes 3/
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	no	-	yes 3/
163.61-7	Product Analytical Methods & Data	Each Product	partially 4/	00003172 00002995	yes, 14 months
163.61-8	Physical/Chemical Properties	Technical or Manufacturing-Use Product	partially	1/	yes 3/

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ Confidential Statements of Formula, EPA Form 8570-4.

2/ The manufacturing process is not sufficiently detailed for technical carboxin or the formulation intermediate.

3/ These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. These requirements must be filled at the time of registration or reregistration.

4/ The analytical methods are of sufficient detail to satisfy the Agency's requirements. However, validation data and results of analysis on at least five typical samples of each product must be submitted

C. Product Specific End-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.61-3	Product Identity & Disclosure of Ingredients	Each Product	partially 1/	2/	yes 3/
163.61-4	Description of Manufacturing Process	Each Product	partially 4/	-	yes 3/
163.61-5	Discussion on Formation of Unintentional Ingredients	Each Product	partially 1/	2/	yes 3/
163.61-6	Declaration & Certification of Ingredients Limits	Each Product	no	-	yes 3/
163.61-7	Product Analytical Methods & Data	Each Product	partially 1/	2/	yes 3/
163.61-8	Physical/Chemical Properties	Each Product	partially 1/	2/	yes 3/

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ Only data specified in the Confidential Statements of Formula EPA Form 8570-4 will be required.

2/ Confidential Statements of Formula, EPA Form 8570-4.

3/ These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. These requirements must be filled at the time of registration or reregistration.

4/ Manufacturing process for Vitavax Flowable Fungicide is the only process adequately described.

C. Product Specific End-Use Products Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If So, due when?
163.81-1	Acute Oral Toxicity	Each Formulation[1/] or Substantially Similar Formulation	partially	00003317[2/] 00003081[4/] 00003082[5/] GS001205[-/]	yes[3/], 14 months
163.81-2	Acute Dermal Toxicity	Each Formulation[1/] or Substantially Similar Formulation	partially	00003314[2/] 00003080[4/] 00005858[6/] 00005866[8/] GS001203[5/]	yes[7/], 14 months
163.81-3	Acute Inhalation Toxicity	Each Formulation[1/] or Substantially Similar Formulation	partially	00003034[2/] 00003083[4/] GS001204[5/]	yes[3/], 14 months
163.81-4	Primary Eye Irritation	Each Formulation[1/] or Substantially Similar Formulation	partially	00003301[2/] 00003035[2/] 00003161[4/] 00005857[6/] 00003005[8/] GS001202[5/]	yes[7/], 14 months
163.81-5	Primary Skin Irritation	Each Formulation[1/] or Substantially Similar Formulation	partially	00003311[2/] 00003162[4/] 00005856[6/] 00005864[8/] GS001206[5/]	yes[7/], 14 months

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.

1/ See Guidance Package for requirements for each formulation or substantially similar formulation.

2/ This study is adequate for the testing of a 75% a.i. wettable powder/dust formulation.

3/ Further testing is required for a 29.52% a.i. soluble concentrate/liquid, 25% a.i. dust, and a 10% a.i. granular formulation.

4/ This study is adequate for the testing of a 34% a.i. ready-to-use formulation.

5/ This study is adequate for the testing of a 17% a.i. flowable formulation.

6/ This study is adequate for the testing of a 29.52% a.i. soluble concentrate/liquid formulation.

7/ Further testing is required for a 25% dust formulation.

8/ This study is adequate for the testing of a 10% a.i. granular formulation.

IV. PRODUCT CHEMISTRY

A. Chemical Identity
B. Manufacturing Process
C. Ingredient Limits in Carboxin Products
D. Product Analytical Methods and Data
E. Physical and Chemical Properties
F. Summary of Data Gaps

A. CHEMICAL IDENTITY

Carboxin is the common name accepted by the American National Standards Institute (ANSI) for the chemical 5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide. Carboxin is also known by the trade name Vitavax® and by the abbreviations DMOC and DCMO. The Chemical Abstracts Registry number is 5234-68-4; the Uniroyal, Inc. internal code numbers as D-735 and F-735; and the EPA Shaughnessy number is 090201. The common name, carboxin, will be used throughout this standard in lieu of other chemical or trade names.

B. MANUFACTURING PROCESS

The specific details of the synthesis process for technical carboxin are considered trade secrets. There are two procedures, and they are detailed in Uniroyal, 19??, MRID 00003296 and Uniroyal, 1976, MRID 00003084. The manufacturing process for the formulation - Vitavax® Flowable Fungicide - has been submitted to the Agency (Uniroyal, 19??, MRID 00003231). This process is also considered a trade secret.

Manufacturing processes for the other products have not been submitted to the Agency.

C. INGREDIENT LIMITS IN CARBOXIN PRODUCTS

A commitment (certification) is required from each registrant that the ingredients and impurities in the product will be maintained within specified limits for as long as the product is offered for sale. Upper and lower limits are required for the active and intentionally added inert ingredients. Upper limits are required for the impurities. These have not been established for any carboxin product.

D. PRODUCT ANALYTICAL METHODS AND DATA

Infrared spectroscopic methods for the assay of carboxin in the technical product and in formulations have been submitted to the Agency, (Puchalsky, 1968, MRID 00003172 and Uniroyal, 19??, MRID 00002995). A titrimetric method has also been submitted for the determination of carboxin in the technical product (Uniroyal, 1960, MRID 00002978). The above-mentioned infrared spectroscopic and titrimetric methods have been published by Stone (1976, MRID 05005076).

Carboxin formulations may be analyzed for the active ingredient by an ultraviolet spectrophotometric method (Harda, 1978, MRID 05003778).

The above mentioned assay methods are sufficiently detailed to satisfy Agency requirements. However, validation data and results of analysis on at least five typical samples of each product have not been submitted. This information will need to be submitted.

E. PHYSICAL AND CHEMICAL PROPERTIES

The following information is for technical carboxin, unless otherwise mentioned.

1. Color

Off-white (Uniroyal, 1977, MRID 00005859 and Confidential Statement of Formula [CSF])

2. Odor

Described as "faint" (Uniroyal, 1977, MRID 00005859 and CSF)

3. Melting Point

Two melting ranges of technical carboxin are 91.5-92.5°C and 98-101°C, reflecting two crystalline structures. In solution the two structures revert to one. It is reported that that there are no differences in biological activity between the two structures (Uniroyal, 1977, MRID 00005859 and CSF).

4. Density or Specific Gravity

Product	Density/Specific Gravity
Technical	1.70
Technical	40-45 lbs/ft^3*
Formulation Intermediate	20-30 lbs/ft^3*
Ready to Use (Flowable)	1.05-1.13 gm/ml
Soluble Concentrate (Liquid)	1.13-1.18 gm/ml

*Bulk density

(Uniroyal, 1977, MRID 00005859 and CSF)

5. Physical State

Product	Physical State
Technical	Crystalline solid
Formulation Intermediate	Solid
Wettable Powder/Dust	Powder
Ready-to-Use (Flowable)	Liquid
Soluble Concentrate	Liquid
Dust	Powder

(Uniroyal, 1977, MRID 00005859 and CSF)

6. Solubility

Solvent	Gm Solute/100 gm solvent @ 25 C
Distilled Water	0.017
Benzene	15
Dimethyl Sulfoxide	150
Acetone	60
Methanol	21
Ethanol	11

(Uniroyal, 1977, MRID 00005859)

7. Stability

Carboxin is readily inactivated by ultraviolet light and sunlight (Buchenour, 1975, MRID 05002823).

8. pH

There are two Ready-to-Use (Flowable) formulations. The pH range for one of these formulations is 7.0-9.0, the other is 6.2-8.2. The pH for the soluble concentrate formulation is 9.0-10.5 (Uniroyal, 1977, MRID 00005859 and CSF).

9. Flammability

Product Type	Flash Point	Test Method
Technical	203 C	C.O.C.*
Ready-to-Use (Flowable)	>93 C	Unreported
Ready-to-Use (Flowable)	102 C	Unreported
Soluble Concentrate (Liquid)	56 C	Unreported

*Cleveland Open Cup Method

(Uniroyal, 1977, MRID 00005859 and CSF)

10. Storage Stability

Three years (Uniroyal, 1977, MRID 00005859).

F. SUMMARY OF DATA GAPS

A detailed manufacturing process for the technical product, the formulation intermediate, and each end-use product except Vitavax® Flowable Fungicide; details on the formation of unintentional ingredients; certification of ingredient limits; validation data and results from analysis on each product; and various physical/chemical properties must be submitted to the Agency.

V. ENVIRONMENTAL FATE

A. Use Summary
B. Environmental Fate Profile
C. Exposure Profile
D. Summary of Data Gaps

A. USE SUMMARY

Carboxin is a systemic fungicide registered for use as a seed treatment for control of smuts and seed rot and seedling blight caused by Rhizoctonia solani. As a single active ingredient, use sites include barley, corn, cottonseed, oats, peanuts, and wheat. Carboxin is also registered for Special Local Needs (FIFRA section 24(c)) as a combined foliar and soil application on peanuts to control Southern blight (in Alabama, Georgia, North Carolina, Oklahoma, South Carolina, and Texas only).

At present six products with carboxin as the sole active ingredient are registered for use: a dust (25% a.i.); a wettable powder/dust (75% a.i.); two ready-to-use flowable liquids (34% and 17.1% a.i.); and two liquid soluble concentrates (both 29.5% a.i.). For SLN use there are two formulations registered: a 34% flowable concentrate and a 4% granular.

Current seed treatment uses and application rates, by formulation, are summarized in Table 1; and SLN combined foliar and soil application rates are summarized in Table 2, on the following pages.

Table 1

Seed Treatment Application Rates

	RATE RANGE (oz. product/100 lb seeds)			
Formulation*	WP/D (75%)	RTU (34% & 17.1%)	D (25%)	SC/L (29.52%)
Crop				
Barley	2-3[a/]	2-3[b/]		
Corn		2-4[b/]	4-6	
Cottonseed	4-8	16[c/]		20[d/]
Oats	1-2	2-3[b/]		
Peanuts	2-6			
Wheat	2-3[a/]	2-3[b/]		

*WP/D- Wettable Powder/Dust

RTU- Ready-to-Use

D- Dust

SC/L- Soluble Concentrate/Liquid

[a/] 4 oz./100 lbs. for seed production purposes only

[b/] 34% Ready to Use Formulation

[c/] 17.1% Ready to Use Formulation

[d/] Limited by registrant to seed treatment by professional applicators only

Table 2

Foliar Application Rates on Peanuts

Formulation*	FC (34%)	G (4%)
State		
Alabama	3 pints/acre[a/]	
Georgia	3 pints/acre[a/]	25 lbs./acre[d/]
North Carolina	3 pints/acre[b/]	25 lbs./acre[d/]
Oklahoma	3 pints/acre[a/]	25 lbs./acre[d/]
	2 pints/acre[c/]	
South Carolina	3 pints/acre[a/]	
Texas	3 pints/acre[a/]	25 lbs./acre[d]
	2 pints/acre[c/]	

* FC- Flowable Concentrate

G- Granular

[a/] Mixed with 20 gallons of water and applied by ground spray

[b/] Mixed with 30 gallons of water and applied by ground spray

[c/] Applied by overhead irrigation only

[d/] Applied by air or ground broadcast

B. ENVIRONMENTAL FATE PROFILE

The available data are insufficient to completely assess the environmental fate of carboxin.

In aqueous solution (under UV light and in the dark) carboxin was oxidized to carboxin sulfoxide, carboxin sulfone, and two unidentified compounds (A and B). The photolytic half-life was less than four hours. After seven days of irradiation in aqueous solution, 40 and 9 percent of the exposed ^{14}C carboxin was present as the unidentified compounds A and B, respectively. Fourteen days later, 57 percent of the radioactivity was present as compound A and 19 percent as compound B. Formation of compound A was accelerated in a 2 percent acetone-water solution (Smilo, 1977, MRID 00003088).

Carboxin was degraded in aerobic soil. The half-life of carboxin was less than one day in loamy sand and silt loam soil, and less than three days in sandy soil, with more than 95 percent of the applied carboxin being degraded within seven days. The major degradation product was carboxin sulfoxide, which represented 31-54 percent of the applied radioactivity at seven days after treatment. Carboxin sulfoxide residue levels declined to 28-49 percent and 19 percent of the applied radioactivity at 30 and 154 days after treatment, respectively. Several minor degradation products were also formed (carboxin sulfone, p-hydroxy carboxin sulfoxide, p-hydroxy carboxin, and $^{14}CO_2$). Carboxin was degraded in sterile soil but at a much slower rate than in nonsterile soil (46-72 percent degraded in seven days). This indicated that the soil metabolism of carboxin under aerobic conditions was both a microbial and chemical process. Carboxin sulfoxide and carboxin sulfone were stable under anaerobic conditions (Chin et al., 1972, MRID 00002935; Chin et al., 1969, MRID 00003041; Chin et al., 1970, MRID 05002176; Chin et al., 1970, MRID 05004996; Dzialo and Lacadie, 1978, MRID 00003225; Dzialo et al., 1978, MRID 00003226; and Spare, 1979, MRID 00005540).

Carboxin was oxidized to carboxin sulfoxide and carboxin sulfone by flavin enzymes found in fungal mitochondria. The fungus Ustilago maydis and isolated mitochondria from Trametes versicolor and Aspergillus niger were capable of oxidizing carboxin to carboxin sulfoxide and carboxin sulfone. This reaction was accelerated under illuminated conditions. A Pseudomonas species oxidized carboxin to carboxin sulfoxide in three days and to carboxin sulfone in seven days (Balasubramanya and Patil, 1976, MRID 05006289). Carboxin sulfone was hydrolyzed to form 5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxylic acid-4,4-dioxide and aniline (Lyr et al., 1974, MRID 05003852). Basillus cereus oxidized carboxin to carboxin sulfoxide and carboxin sulfone in Nile River water containing added sludge (El-Dib and Aly, 1976, MRID 05003218; Bachofer et al., 1973, MRID 05005110; and Michail et al., 1975, MRID 05004129).

The effect of carboxin on microorganisms is varied. At two ppm, carboxin had a slight inhibitory effect on fungal populations for 21 days and inhibited starch degradation (33-55 percent) for three days. A severe inhibitory effect on nitification (75-85 percent) occurred from 7 to 14 days after treatment with carboxin at two ppm. This inhibition may have been due to carboxin sulfoxide

since more than 95 percent of the carboxin was degraded within seven days (Spare, 1979, MRID 00005540). Carboxin at 50 ppm inhibited dehydrogenase activity in fungi 30 percent (Lyr et al., 1974, MRID 05003852).

In the laboratory, carboxin inhibited two strains of nitrogen-fixing bacteria in nutrient agar. When applied to inoculated seed at 0.1-0.2 ppm (approximate actual application rate), carboxin inhibited nodulation of soybeans inoculated with Rhizobium japonicum by up to 83 percent and completely inhibited nodulation of Vigna anguiculata inoculated with rhizobia strains CB 756 and XS 30 however, treated uninoculated seeds planted in soil containing rhizobia strains CB 756 and XS 30 produced nodules (Curley and Burton, 1975, MRID 05003947). Azotobacter chroococcum and Rhizobium trifolii in nutrient agar were not inhibited by carboxin at two and ten ppm, respectively. Although carboxin sulfone at 25-150 ppm decreased nitogen fixation by Rhizobia trifolii 20-25 percent, it is doubtful that carboxin sulfone will be present in concentrations greater than 0.05 ppm as a result of the application of carboxin. Of the 23 common soil bacteria and fungi exposed to carboxin, only four experienced growth reductions of 20 percent or more at the lowest concentration of 2.5 ppm (Spare, 1979, MRID 00005540; El-Dib and Aly, 1976, MRID 05003218; Fisher, 1976, MRID 05002757; and Kritzman et al., 1977, MRID 05002989).

Both carboxin and carboxin sulfoxide were mobile in soil, with about half of the applied ^{14}C carboxin leaching through the twelve inch column of clay loam soil (Lacadie et al., 1978, MRID 00003227 and Dannals et al., 1976, MRID 00003114). Lacadie et al. (1978, MRID 00003229) found that radiolabeled carboxin aged in sandy soil was mobile. Approximately 17 percent of the applied radioactivity was recovered in the leachate from a twelve inch soil column. One-third of the radioactivity was in the top three inches and one-fourth was in the three to six inch segment of the soil column. Carboxin, carboxin sulfoxide and carboxin sulfone were identified in the leachate and accounted for 0.3, 3.3 and 0.5 percent respectively of the applied radioactivity.

Smyser (1979, MRID 00005541) found that there is a low potential for carboxin adsorption to a sandy loam soil (Freundlich adsorption coefficient was K=0.78). The calculated desorption coefficient was K=1.10.

A simulated field dissipation study was conducted by Cardona et al. (1976, MRID 00003087). One month after a sandy loam soil was treated with radiolabeled carboxin (1 lb./acre) only 4 percent of the applied carboxin had not degraded. The major degradation products were carboxin sulfoxide (31-33 percent) and an unidentified compound II (6-18 percent). Two months after treatment the carboxin could not be detected and only 4 percent of the sulfoxide and 2-3 percent of compound II remained. After one year, approximately 75-80 percent of the radioactivity remaining was found in the top six inches. Leaching to at least 11 inches was indicated by the detection of radioactivity at that depth. The detection of the compound, its metabolites, or degradation products at a depth of 11 inches one year after application indicated that carboxin aged residues were persistent and mobile.

Dannals et al. (1976, MRID 00003114) found ^{14}C residues in wheat (seed), beets (top and root) and lettuce planted in a sandy loam soil four months after treated with ^{14}C-carboxin at 1 lb. a.i./acre. The concentration of oxathiin-labeled residues present in those crops were 1.5-60 times higher than the concentration of aniline-labeled residues.

A field study by Uniroyal Chemical (1978, MRID 00003224) showed that carboxin residues were not taken up in turnip roots planted 59 days after treatment with carboxin (Vitavax® 3F). Carboxin residues were less than 0.2 ppm, the sensitivity of the method used, in turnip greens and rye seed planted after treatment. However, the analytical method was not sensitive enough to determine conclusively that residues less than 0.2 ppm were not taken up by rotational crops.

Bluegill sunfish exposed to carboxin at a constant concentration of 0.012 ppm for 30 days accumulated the compound at 0.50 ppm with a bioaccumulation factor of 45. A plateau was not reached during the 30-day exposure period, thus indicating that there is a potential for carboxin residues to accumulate in sunfish. Residue levels were increasing at the end of the exposure period, indicating that continued uptake of ^{14}C residues could occur because carboxin oxidative products (carboxin sulfoxide and carboxin sulfone) are stable and persistent in water and probably would be available for uptake (accumulation) beyond 30 days. After a 14-day depuration period, 23 percent (0.11 ppm) of the maximum ^{14}C residue levels remained in the sunfish (Kuc and Doebbler, 1979, MRID 00005544). Catfish exposed to carboxin and its aged residues at 0.05 ppm accumulated 0.36 ppm with a bioaccumulation factor of 5 after exposure for 22 days. The ^{14}C residue levels in the whole fish tissue had declined by approximately 15 percent (to 0.31 ppm) at 30 days. After a 14-day depuration period, 32 percent (0.12 ppm) of the maximum ^{14}C residue levels in catfish remained (Kuc and Doebbler, 1979, MRID 00005545). Since 40-80 percent of the residues in the bluegill sunfish and over 50 percent of the residues in the catfish were unextractable, the identity of the unextractable compounds cannot be established.

In summary, carboxin is rapidly degraded to carboxin sulfoxide and carboxin sulfone (greater than 95 percent within seven days) by microbial and chemical processes in aerobic soil. Based on the mobility data available, carboxin was not tightly adsorbed to sandy loam soil and was mobile in soil columns under rapid leaching conditions, indicating a potential to contaminate ground water. Mobility of carboxin aged in soil was mitigated by its degradation to carboxin sulfoxide and carboxin sulfone. However, carboxin sulfoxide and small amounts of carboxin sulfone were mobile in soil columns, indicating their potential to reach ground water.

Carboxin severely yet briefly inhibits starch degradation and when used as a seed treatment on inoculated seeds severely inhibits formation of nodules by some strains of nitrogen-fixing bacteria. Therefore, the use of carboxin on inoculated legumes (currently used on peanuts) may have an effect on symbiotic nitrogen fixation and therefore on the amounts of nitrogen available to peanuts.

Carboxin residue levels of 0.50 and 0.36 ppm accumulated in bluegill sunfish and catfish. Carboxin sulfoxide was the major carboxin metabolite in bluegills, but the carboxin residues in catfish were not identified.

Carboxin sulfoxide was the major degradation product of carboxin in soil and water. Carboxin sulfoxide was present in aerobic soil for at least five months and was stable in anaerobic soil, Carboxin was photodegraded to carboxin sulfoxide and two unidentified compounds. Carboxin sulfoxide may inhibit nitrification in soil.

Carboxin sulfone (the fungicide oxycarboxin) is a minor product of carboxin degradation. It will not be present in soil in a sufficient concentration to result in significant exposure.

C. EXPOSURE PROFILE

1. Seed Treatment Formulations Only

Exposure from this use pattern to humans, livestock, and wildlife via spray drift is unlikely because the chemical is not applied aerially. Carboxin and its residues have been shown to be mobile in soil indicating a potential for groundwater contaminate. Although the mobility of carboxin aged in soil was mitigated by its degradation to the sulfoxide and sulfone, these degradates were also mobile in soil. However, since single active ingredient formulations of carboxin are used primarily as seed treatments, the use pattern minimizes the potential exposure of humans and domestic animals to carboxin and its residues via groundwater contamination. Carboxin residues indicated a potential to accumulate in bluegill sunfish and catfish. However, as formulations containing the single active ingredient carboxin are used primarily in seed treatments, this potential hazard is minimized. Potential exposure of humans by ingestion of carboxin residues in rotated crops is also minimized by this use pattern.

Potential exposure of wildlife exists through the ingestion of treated seeds. Mechanically planted seeds may be left uncovered or partially covered at the end of rows, and therefore wildlife, especially birds, could ingest treated seeds. Data necessary to estimate the nature and extent of such exposure are unavailable.

The greatest potential for human exposure exists during seed treatment, most of which is done by seed processors or seed companies. Respiratory exposures may be especially high from the use of dust formulations, and commercial applicators are switching to the flowable concentrate to reduce such exposure. Dermal exposure from handling treated seed is expected to be low since most seeds are mechanically planted.

2. Special Local Need Registrations

a. Flowable Concentrate

Exposure to humans, livestock and wildlife via spray drift is unlikely because the product is not applied aerially. Exposure by spray drift as a result of ground application is not expected because of the use directions which state that the spray solution should be directed to the crown of the plant and pegging zone as a course spray. Direct exposure to humans by overhead irrigation of plants is expected to be minimal due to the dilution directions involved in its application. However, dermal, ocular and oral exposure to humans may occur from drinking and washing of face and hands with irrigation water. Wildlife and domestic animals may potentially be exposed by drinking the irrigation water. Carboxin and its residues have been shown to be mobile in soil indicating a potential to runoff and/or contaminate ground water. The data necessary to develop a quantitative assessment of carboxin and its residues to contaminate ground water are not available. Carboxin residues indicated a potential to accumulate in bluegills and catfish. The Agency does not currently have data to develop a quantitative assessment of fish exposure to residues of carboxin in adjacent ponds as a result of runoff. Potential exposure of humans to carboxin residues by ingestion of rotated crops is increased by the increased dosage and the number of applications involved in the flowable concentrate use on peanuts. The Agency does not currently have data to estimate the nature and extent of such exposure.

b. Granular Formulation

Exposure is possible from the drift of dust particles from aerial applications of granulars. However, little or no information is presently available on the aerial application of granular fungicides. Potential exposure of humans to carboxin and its degradation products by ingestion of rotated crops is increased by the increased dosage and number of applications involved in the granular product use on peanuts, since the granular product falls predominantly on the ground with little intercepted by peanut foliage. Because of increased levels of residues, the preharvest interval has been increased to 60 days. Exposure by mobility and accumulation in fish is similar to the flowable concentrate, but the exposure is increased because of the use pattern for the granular product.

D. SUMMARY OF DATA GAPS

A number of the guideline requirements have been partially fulfilled by the data submitted. However, data are still needed to adequately assess the environmental fate of carboxin. The specific deficiencies can be found in the Data Requirements Charts in Chapter III. The data gaps are: hydrolysis, photodegradation, aerobic and anaerobic soil metabolism, terrestrial field dissipation, and accumulation in rotational crops.

VI. TOXICOLOGY

A. Toxicology Profile
B. Human and Domestic Animal Hazard Assessment
C. Summary of Data Gaps

A. TOXICOLOGY PROFILE

1. Technical Carboxin

a. Acute Effects

A limited amount of information was available to assess the acute oral toxicity of technical carboxin. The oral LD_{50} in rats was 3.82 ± 0.35 g/kg which is sufficient to assign technical carboxin to Toxicity Category III (Carson, 1965, MRID 00003065).

An acute dermal toxicity test was conducted in rabbits (Carson, 1965, MRID 00003066). The data show that when applied as a 50% aqueous slurry, technical carboxin causes no mortality at levels of 8 g/kg, which is sufficient to assign it to Toxicity Category III.

Babish (1977, MRID 00003116) reported that exposure for one hour to a concentration of 20 ml/l of technical carboxin did not cause mortality in rats in an acute inhalation toxicity test. However, due to inappropriate testing protocols, this study must be repeated.

In a primary dermal irritation study conducted on rabbits, 0.5 gm of technical carboxin was applied to the skin and did not cause irritation (Babish, 1977, MRID 00003119). This study indicates that technical carboxin is not a potential skin irritant and may be assigned to Toxicity Category IV.

b. Subchronic Effects

Sufficient data were available to assess the subchronic dietary and dermal effect of technical carboxin. In the rat 90-day feeding study the No Observable Effect Level (NOEL) was 200 ppm of carboxin in the diet. At the 600 ppm level, the effects noted were degenerative renal changes (Ozer, 1966, MRID 00003063). In the two-year dog feeding study the NOEL was 600 ppm (Holsing, 1969, MRID 00003030). In addition, in a 21-day dermal study, rabbits treated with 3.0 g/kg did not produce any treatment related effects (Holsing, 1968, MRID 00003216). No data were available to assess the subchronic inhalation toxicity of technical carboxin. However, the requirements of these data is reserved pending the final results of the acute inhalation study.

c. Chronic Effects

In a screening study, groups of rats were fed for two years diets containing 0, 300, 1,000 or 3,000 ppm of technical carboxin (Holsing, 1969, MRID 00003152). A NOEL was not established in this study because the dose levels were too high. However, in a subsequent chronic feeding study over a two year period,

rats were fed diets containing 0, 100, 200, or 600 ppm of technical carboxin (Holsing, 1969, MRID 00003031). This study indicated that the NOEL is 200 ppm. At the 600 ppm level the effects were poor survival and weight gain depression. These data are sufficient to satisfy the requirement for chronic feeding.

No evidence of oncogenicity was indicated in either of the two-year feeding studies (Holsing, 1969, MRID 00003031 and Holsing, 1969, MRID 00003152). However, oncongenic testing in a second species (preferably the mouse) is required.

A teratology study was conducted in rats by Knickerbocker (1977, MRID 00003120). Technical carboxin at doses as high as 4.0 mg/kg/day did not produce any maternal toxicity. However, teratogenicity testing is still required in a second species.

In a three generation reproduction study, rats were fed diets containing 100, 200, and 600 ppm technical carboxin (Holsing, 1968, MRID 00003032). There were no treatment related effects on reproductive performance. The NOEL was established at 200 ppm.

d. Mutagenicity

Mutagenicity testing is incomplete. In a study by Brusick (1977, MRID 00003118) two different types of tests for detecting gene mutations were reported. Carboxin was tested in the Salmonella typhimurium reversion assay with and without a rat liver microsome metabolic activation system. No increases in reversion frequency were detected in either assay. Carboxin was also tested in a mutation assay system using Saccharomyces cerevisiae, but procedures in this assay were inadequately described. Additional mutagenicity testing is required.

e. Metabolism

Kennedy (1971, MRID 00002943) reported on the distribution and excretion of ^{14}C carboxin in rats. Between 88 and 99 percent of the compound was recovered, most within 24 hours of treatment. The urine contained 42-89 percent of the administered ^{14}C and the feces contained 10-45 percent. The remainder was found in the animal's tissues and organs.

In a companion study, Kennedy (1971, MRID 00002944) characterized the ^{14}C activity in urine and feces using thin layer chromatography and liquid scintillation. Carboxin sulfoxide accounted for 27-45 percent of the ^{14}C in the 24 hour sample and 47-56 percent in the 72 hour sample. Three additional urinary components were detected but not identified, and the parent compound was not present. The major component found in the feces (19-36 percent of fecal ^{14}C) was tentatively identified as carboxin sulfone.

These studies collectively provide sufficient information about the metabolism of carboxin in animals.

2. End-Use Carboxin

Acute toxicity (oral, dermal, and inhalational) and irritation testing (eye and dermal) is required for each formulation or substantially similar formulation.

a. Acute Effects- Oral

One test (Matthews, 1970, MRID 00003317) is available on the acute oral LD_{50} of a 75% wettable powder/dust formulation. The LD_{50} value for this formulation in albino rats is greater than 2 g/kg. This is sufficient information to assign this formulation to Toxicity Category III.

Two acute oral toxicity studies were conducted that together show that the LD_{50} for the 34% ready-to-use liquid formulation in rats is greater than 5 ml/kg, or 5 g/kg (Babish, 1977, MRID 00003081 and Babish, 1977, MRID 00003082). This is sufficient information to place this formulation in Toxicity Category IV.

The acute oral LD_{50} of the 17% flowable formulation was found to be greater than 5 ml/kg in rats (Babish, 1977, MRID GS001205). This formulation falls into Toxicity Category IV.

b. Acute Effects-Dermal

A dermal toxicity study was conducted on rabbits using a 75% wettable powder/dust formulation (Matthews, 1970, MRID 00003314). No deaths and no signs of toxicity were observed at doses up to 10 g/kg. This is sufficient information to assign this formulation to Toxicity Category III.

The acute dermal LD_{50} value of a 34% ready-to-use formulation was found to be greater than 20 ml/kg or 20 g/kg in albino rabbits (Babish, 1977, MRID 00003080). This is sufficient information to assign this formulation to Toxicity Category IV.

The acute dermal LD_{50} value of a 29.52% soluble concentrate/liquid formulation was found to be greater than 5 g/kg for albino rabbits (Stevens, 1979, MRID 00005858). This information is sufficient to assign this formulation to Toxicity Category III.

The acute dermal LD_{50} of a 10% granular formulation is greater than 20 g/kg in albino rabbits (Babish, 1977, MRID 00005866). No deaths occurred in the 14 day observation period. Decreased activity and anorexia were the only toxic signs. This is sufficient information to assign this formulation to Toxicity Category IV.

The acute dermal LD_{50} of a 17% flowable formulation is greater than 20 g/kg in rabbits (Babish, 1977, MRID GS001203). This test substance falls within Toxicity Category IV.

c. Acute Effects- Inhalation

Binnes et al. (1969, MRID 00003034) found that the LC_{50} value of a 75% wettable powder/dust formulation is greater than 5 mg/l for rats. No animals died, but test animals displayed a nasal discharge during exposure. This formulation can be assigned a Toxicity Category III.

Rats were exposed to a concentration of 20 mg/l of a 34% ready-to-use formulation. No mortality was produced, but ataxia was observed (Babish, 1977, MRID 00003083). These data indicate that this formulation can be assigned to Toxicity Category IV.

The inhalation LC_{50} of a 17% flowable formulation is greater than 20 ml/l in rats (Babish, 1977, MRID GS001204). This test substance falls within Toxicity Category IV.

d. Acute Effects- Eye Irritation

Two studies were conducted using a 75% wettable powder/dust formulation. Holsing (1968, MRID 00003035) placed 100 mg of the formulation in the eyes of rabbits and observed marked and persistent conjunctival effects, iris irritation, and corneal opacity. In general, the irritation and corneal damage were still present after 14 days. Bailey (1976, MRID 00003301), also placed 100 mg of the 75% wettable powder formulation into one eye of each rabbit and noted corneal opacity within 72 hours, and damage to the iris, although neither of these effects persisted for seven days. Conjunctival effects occurred and persisted for seven days. This information is sufficient to assign this formulation to Toxicity Category I, however, if the registrant wishes to repeat an eye irritation study for the required 21 days, the Toxicity Category may be lowered.

Testing a 34% ready-to-use formulation for eye irritation, Babish (1976, MRID 00003161) found no irritation to the conjunctiva, iris or cornea of the eyes of the test rabbits. This formulation can be assigned to Toxicity Category IV.

Stevens (1979, MRID 00005857) tested a 29.52% soluble concentrate/liquid formulation for eye irritation. Results show transient conjunctival effects, however no iris or cornea irritation was observed. These observations are sufficient to assign this formulation to Toxicity Category IV.

A 10% granular formulation was instilled in one eye (unwashed) of each of six rabbits (Bailey, 1976, MRID 00003005). This treatment did not produce corneal damage, but did cause slight conjunctival effects, including redness, swelling, and discharge. These effects started within 72 hours in all six rabbits and persisted in four rabbits for seven days. These results are sufficient to place this formulation in Toxicity Category III, however, if the registrant wishes to repeat an eye irritation study for the required 21 days, the Toxicity Category may be lowered.

A 17% flowable formulation was a mild to moderate eye irritant to rabbits which produced corneal opacity persisting over 72 hours, but less than seven days

(Babish, 1977, MRID GS001202). The average Draize score was 0.66, which is sufficient to place this formulation into Toxicity Category III.

e. Acute Effects- Dermal Irritation

No irritation was observed at 24 and 72 hours after a 75% wettable powder/dust formulation was applied to the skin of rabbits (Matthews, 1970, MRID 00003311). These results are sufficient to assign this formulation to Toxicity Category IV.

Moderate irritation to the intact and abraded skin of albino rabbits was observed at 24 and 72 hours after application of a 34% ready-to-use formulation (Babish, 1976, MRID 00003162). Erythema and edema were also noted. These results were sufficient to assign this formulation to Toxicity Category IV.

The 29.52% soluble concentrate/liquid formulation was severely irritating when applied to both intact and abraded skin of albino rabbits. Moderate to severe erythema and edema persisted throughout the 72 hour observation period (Stevens, 1979, MRID 00005856). These results were sufficient to assign this formulation to Toxicity Category III.

No irritation was observed at 24 and 72 hours after a 10% granular formulation was applied to the skin of rabbits (Babish, 1977, MRID 00005864). These results are sufficient to assign this formulation to Toxicity Category IV.

A 17% flowable formulation produced edema for 72 hours when tested on rabbits (Babish, 1977, MRID GS001206). The average Draize score was 0.50, indicating that this formulation is not classified as a skin irritant and can be placed into Toxicity Category IV.

B. HUMAN AND DOMESTIC ANIMAL HAZARD ASSESSMENT

1. Technical

The information available to assess potential hazard as a result of chronic exposure is incomplete (see the Toxicity Profile for details). However, the available data suggest carboxin poses little or no discernible risk in regards to oncogenic, teratogenic and reproductive effects to man or domestic animals. In addition, the data on acute oral, acute dermal and primary dermal irritation indicate the products containing carboxin are in Toxicity Category III. No data were available to assess the acute inhalation, primary eye irritation and dermal sensitization hazard.

2. Wettable Powder/Dust (WP/D)

The 75% WP/D formulation had low acute oral, acute dermal, acute inhalation and primary skin irritation potentials. However, the overriding toxic effect is the primary eye irritation category. Two irritation studies show that this formulation is a moderate to severe eye irritant and appropriate labelling and caution (Category I) is necessary.

3. Ready-to-Use (RTU)

The 34% and 17% RTU formulations, according to the acute oral, acute dermal, acute inhalation, primary eye, and primary dermal irritation, are in Toxicity Category IV (low hazard potential).

4. Soluble Concentrate/Liquid (SC/L)

The 29.5% SC/L formulation, according to the acute dermal, primary eye irritation, and dermal irritation, is in Toxicity Category III. This is due to the moderate dermal irritation effects.

5. Granular

The 10% granular formulation showed low dermal toxicity and irritation, however there was moderate eye irritation. This formulation can be placed in Toxicity Category III.

C. SUMMARY OF DATA GAPS

The following tests are required for the reregistration of carboxin: acute oral toxicity (25% dust, 29.5% soluble concentrate/liquid, and 10% granular), acute dermal toxicity (25% dust), primary eye irritation (technical product and 25% dust), skin irritation (25% dust), acute inhalation toxicity (10% granular, 25% dust, 29.5% soluble concentrate/liquid), and the following tests on the technical product only: dermal sensitivity, oncogenicity, teratogenicity, and mutagenicity.

VII. RESIDUE CHEMISTRY

A. Residue Chemistry Profile
B. Labeling Requirements
C. Summary of Data Gaps

A. RESIDUE CHEMISTRY PROFILE

1. Uptake and Distribution and Metabolism in Plants

Data obtained by a variety of methods show that carboxin is systemic in plants. Extracts of plants grown from carboxin-treated seed or immersed in a carboxin solution have been shown by bioassay methods to contain fungicidal residues (Verma and Vyas, 1976, MRID 05001172; Thapliyal and Sinclair, 1971, MRID 05001304; Thapliyal and Sinclair, 1970, MRID 05001302; Bolkan and Milne, 1975, MRID 05002793). Fungicidal residues persist up to 29 days in some plants (Bolkan and Milne, 1975, MRID 05002793).

The distribution of residues derived from phenyl-^{14}C- or oxathiin-^{14}C-carboxin in cotton, wheat, barley, soybean, and bean plants has been studied (Leroux and Gredt, 1972, MRID 05006363; Ambro-Balint, 1974, MRID 05013368; Briggs et al., 1974, MRID 05002886; Thapliyal and Sinclair, 1971, MRID 05001304; Kirk et al., MRID 1969, 05003664; Berggren and Pinckard, 1973; MRID 05003673; Snel and Edgington, 1970, MRID 05003663; Chin et al., 1970, MRID 05002177; Chin et al., 1969, MRID 00003044; Chin et al., 1972, MRID 00002941). Bioassay data show that carboxin is systemic in all species studied. The pattern of distribution of carboxin and its metabolites within plants is variable, depending upon the species examined, the length of exposure to the labeled compound. Data obtained by methods capable of detecting the total radiolabeled residue (combustion technique, radioautography) show that roots, lower stem and the earliest leaves contain the bulk of the radiolabeled chemical (Kirk et al., 1969, MRID 05003664; Berggren and Pinckard, 1973, MRID 05003673; Snel and Edgington 1970, MRID 05003663; Chin et al., 1969, MRID 00003044). Radiolabeled carboxin distribution within plants was similar when the ^{14}C label was in the oxathiin or phenyl rings of carbon (Briggs et al., 1974, MRID 05002886; and Chin et al., 1969, MRID 00003044).

The predominant metabolite of carboxin in wheat, beans, and barley plants grown from ^{14}C-carboxin-treated seed is the sulfoxide derivative of carboxin (Leroux and Gredt, 1972, MRID 05006363; Ambro-Balint, 1974, MRID 05013368; Snel and Edgington, 1970, MRID 05003663; Chin et al., 1970, MRID 05002177). Small amounts of carboxin sulfone (oxycarboxin) have been found in treated barley and wheat (Chin et al., 1970, MRID 05002177), and the p-hydroxylated derivative of carboxin has been identified in barley (Briggs et al., 1974, MRID 05002886). As crops mature, insoluble anilide complexes (these complexes of carboxin or carboxin derivatives with macromolecules such as lignin are insoluble in water and organic solvent and liberate aniline upon hydrolysis) increase (Briggs et al., 1974, 05002886; Snel and Edgington, 1970, MRID 05003663; Chin et al.,1970, MRID 05002177; Chin et al., 1972, MRID 00002941). Seven weeks after planting, acetone-insoluble residues were 23 percent of the total residue in barley and 40 percent in wheat (Chin et al., 1970, MRID 05002177). Polar metabolites of carboxin also increase during crop maturation (Leroux and

Gredt, 1972, MRID 05006363; Snel and Edgington 1970, MRID 05003663), but do not contribute significantly to the total residue in aerial portions of plants (Leroux and Gredt, 1972, MRID 05006363).

The uptake, distribution and metabolism of carboxin in plants has been adequately defined for the registered seed treatments. The residues of concern are: carboxin, carboxin sulfoxide, carboxin sulfone and insoluble anilide complexes.

2. Metabolism in Food-Producing Animals

Data on the metabolism of carboxin in food-producing animals have not been submitted to the Agency.

The Agency is not requiring an animal metabolism study to support the seed treatment use of carboxin. Data from a ruminant feeding study (see Residues in Animals) in conjunction with data on residues in crops (see Residues in Plants) indicate that total residues would be low or undetectable in tissues of animals fed commodities grown from seed treated with carboxin at application rates now permitted.

Additional metabolism and residue studies are being required to support the combined foliar and soil application to peanuts. If these studies show a higher residue level than that resulting from seed treatment, metabolism studies may be necessary on ruminants and poultry, since peanut meal, hulls, and soapstock are feed items.

3. Analytical Methods

A colorimetric method (Lane, 1970, MRID 05002737), by which carboxin and carboxin derivatives are determined as aniline, has been used to obtain most residue data on growing crops. Sensitivity of this method is 0.2 ppm.

Some residue data were obtained by an earlier version of the aforementioned colorimetric method (Lane, 1966, MRID 00003058).

A gas chromatographic method also based on determination of aniline has been used to gather data on residues in mature crops (Sisken and Newell, 1971, MRID 00003335). Sensitivity of the method is 0.2 ppm.

Recovery data for both methods are acceptable. No pesticide with tolerances on commodities on which carboxin is used has been found to interfere with the GLC method. Only pesticides hydrolyzable to 3,4-dichloroaniline, such as diuron and linuron, have been found to interfere with the colorimetric method (Lane and Sisken, 19??, MRID 00025467; Uniroyal Chemical, 1970, MRID 00025468; Uniroyal Chemical, 197?, MRID 00025483; Uniroyal Chemical, 1975, MRID 00002919; Uniroyal Chemical, 1975, MRID 00003054; Uniroyal Chemical, 1974, MRID 00002905; and Uniroyal Chemical, 1972, MRID.00002940).

The colorimetric method determines most carboxin derivatives including insoluble anilide complexes, but samples analyzed by the GLC method are not

likely to detect insoluble complexes. There have been no data submitted indicating the fraction of total residues determined by either method.

The colorimetric and GLC methods are subject to considerable interferences in untreated crop samples. A modified colorimetric method for residues hydrolyzable to aniline in meat, milk and eggs has been submitted (UniroyalChemical, 1973, MRID 00002857). The method differs from that of Lane in that samples undergo extraction and column-chromatography clean up steps prior to steam distillation. Sensitivity of the method is 0.2 ppm for meat and meat by- products, 0.05 ppm for eggs, and 0.02 - 0.05 ppm for milk. Untreated sample blanks are low, recovery data are adequate and other pesticide and pesticides with tolerances on meat, milk, and eggs do not interfere with the determination of carboxin. The method has been successfully tried out in an EPA laboratory and is published in the Pesticide Analytical Manual (PAM). This method has not been validated for commodities other than meat, milk and eggs.

In summary, both the colorimetric method of Lane and the GLC method of Sisken and Newell are suitable for obtaining residue data, although the latter method may not determine insoluble aniline complexes. Neither method is suitable for tolerance enforcement, but a modification of the colorimetric method is acceptable for enforcement of tolerances on meat, milk, and eggs. The modified method may be acceptable for tolerance enforcement on crops, if data, including data showing that the method determines insoluble anilide complexes, are submitted and the method was validated.

4. Residues in Plants

The following tables of residue data reflect the use of carboxin as a seed treatment. Residues in or on immature crops were analyzed primarily by the colorimetric method of Lane (1970, MRID 05002737), and residues in mature crops by the GLC method of Sisken and Newell (1971, MRID 00003335).

The residue level on carboxin-fortified plant samples did not change after seven months of subzero storage (colorimetric method, Stone, 1969, GS001201) or on fortified seed samples stored for 11 months at room temperature (GLC method, Sisken and Lane, 1970, MRID 00025466).

Corn: Residue data have been obtained on fodder (whole immature plants), forage (stalks at harvest), ears (without husks), and grain. Data were gathered in Illinois, Iowa, Indiana, Minnesota, Washington, Nebraska and North Carolina:

RESIDUE SUMMARY

SAMPLE	PHI (weeks)	RATE(s) (oz/cwt seed)	RESIDUE DISTRIBUTION ppm (as carboxin) <0.2	0.2-0.5	>0.5
DUST 1/					
Fodder	4-21	1.5,3.0	12	0	0
Forage	22-23	1.0-3.0	6	0	0
Ears	21-25	1.0-3.0	8	0	0
grain	21-24	1.5-6.0	8	0	0
READY-TO-USE (FLOWABLE) 2/					
Fodder	4	1.4-2.7	0	1	1*
Fodder	5-9	1.4-2.7	11	1	0
Forage	15-26	0.7,4.0	10	0	0
Ears	15-26	0.7,4.0	10	0	0
SOLUBLE CONCENTRATE-LIQUID 3/					
Fodder	10-15	1.1	8	0	0
Forage	17-29	1.1	5	0	0
Ears	9-17	1.1	6	0	0
Grain	14-17	1.1	2	0	0

[*] (1.1 ppm)
1/ Uniroyal Chemical, 197?, MRID 00025483
2/ Uniroyal Chemical, 1973, MRID 00005852
3/ Uniroyal Chemical, 1975, MRID 00003356

COTTONSEED: Data on residues in whole cotton plants, seed, and in proceeded fractions of seed were obtained in California, Georgia, Mississippi, and Florida:

SAMPLE	PHI (weeks)	RATE(S) (oz/cwt seed)	RESIDUE DISTRIBUTION ppm (as carboxin) <0.2	0.2-0.5	>0.5
FLOWABLE FUNGICIDE 1/					
Seed	28-30	2.8-12.8	9	0	0
WETTABLE POWDER 2/,3/					
Whole plant	2-4	3-12	0	0	13*
Whole plant	5-8	3-12	4	3	7**
Whole plant	10-14	3-12	6	2	0

[*] (2-32 ppm)
[**] (0.6-1.2 ppm)
1/ Uniroyal Chemical, 1973, MRID 00003129
2/ Uniroyal Chemical, 1970, MRID 00025468
3/ Uniroyal Chemical, 1967, MRID 00003185

Residues declined with a half-life of 5 days. Residues were less than 0.2 ppm in oil and meal from processed cottonseed grown from seed treated with 6 or 12 oz. carboxin per 100 lb. of seed (Sisken, 1970, MRID 00002938).

PEANUTS: Data on whole plants, peanut seed, meal and oil from processed seed, and on hulls were gathered from Georgia, North Carolina, Florida, and Texas:

SAMPLE	PHI (weeks)	RATE(s) (oz/cwt seed)	RESIDUE DISTRIBUTION ppm (as carboxin) <0.2	0.2-0.5	>0.5
WETTABLE POWDER[1/,2/]					
Whole plant	2-4	4.5,9.0	0	2	8*
Whole plant	4-7	4.5,9.0	3	2	3**
Whole plant	8-10	4.5,9.0	4	2	2***
Residues in whole plants declined with a half-life of 4-5 days.					
Hay[3/]	20	4.5,9.0	4	0	0
Hulls[4/]	20	4.5,9.0	4	0	0
Hulls[5/]	17	2.25,4.5	4****	0	0
Whole seed[5/]	17	2.25,4.5	4****	0	0
Meal[5/]	17	2.25,4.5	4****	0	0
Oil[5/]	17	2.25,4.5	4****	0	0

[*] (1.3-53 ppm)
[**] (1.3-3.6 ppm)
[***] (0.7-0.8 ppm)
[****] The formulation contained ^{14}C-carboxin. All residues were less than 0.05 ppm.

1/ Uniroyal Chemical, 1970, MRID 00025468
2/ Uniroyal Chemical, 1969, MRID 00003045
3/ Uniroyal Chemical, 1974, MRID 00002905
4/ Uniroyal Chemical, 1974, MRID 00002903
5/ Collier et al., 1974, MRID 00003300

Additional residue studies are required to support the combined foliar and soil application to peanuts.

SMALL GRAINS: Data have been obtained in Idaho, Illinois, Utah, Kansas, North Dakota, Texas, and Manitoba on residues in whole plants and grain of oats, barley and wheat.

SAMPLE	PHI (weeks)	RATE(s) (oz/cwt seed)	RESIDUE DISTRIBUTION ppm (as carboxin) <0.2	0.2-0.5	>0.5
DUST					
Wheat-whole plants[1]	6	1.5,3.0	2	0	0
Wheat-grain[2]	17-19	1.5,3.0	4	0	0
Wheat-straw[2]	17-19	1.5,3.0	4	0	0
Barley-grain[3]	18	1.5,3.0	2	0	0
Barley-straw[3]	18	1.5,3.0	2	0	0
Oats-grain[4]	23	1.5,3.0	2	0	0
Oats-straw[4]	23	1.5,3.0	2	0	0
READY-TO-USE (FLOWABLE)[5]					
Wheat-whole plants	4	1.2-4.0	2	2	6*
Wheat-whole plants	6-12	1.2-2.0	6	3	0
Wheat-whole plants	6-12	2.4-4.0	4	1	4**
Wheat-grain	12-40	1.2-5.6	12	0	0
Wheat-straw	12-40	1.2-4.0	10	0	0
Barley-whole plants	4	1.2-4.0	2	4	0
Barley-whole plants	6-12	1.2-2.4	7	1	0
Barley-whole plants	6-12	4.0	2	1	1#
Barley-grain	12-34	1.2-4.0	6	0	0
Barley-straw	12-34	1.2-4.0	6	0	0
WETTABLE POWDER/DUST					
Wheat-whole plants[6]	4-11	4	8	6	0
Wheat-whole plants[7]	4-11	8	8	4	2##
Wheat-straw[7]	14-39	3-6	8	0	0
Barley-whole plants[6,8]	2-3	3-8	0	0	4$
Barley-whole plants[8]	4-11	3-4	14	4	0
Barley-whole plants[8]	4-11	8	6	4	1##
Barley-grain[8]	14-41	4-12	8	0	0
Oats-whole plants[8]	6-11	4-12	9	3	0

Residues in whole plants declined with an approximate half-life of 10 days[5,6,8]

[*] (0.8-1.8 ppm)
[**] (0.6-0.7 ppm)
[#] (0.8 ppm)
[##] (0.6 ppm)
[$] (0.9-13.3 ppm)

1/ Uniroyal Chemical, 1978, MRID 00003219
2/ Uniroyal Chemical, 1978, MRID 00003218
3/ Uniroyal Chemical, 1977, MRID 00003221
4/ Uniroyal Chemical, 1978, MRID 00003220
5/ Uniroyal Chemical, 1973, MRID 00003158
6/ Uniroyal Chemical, 1969, MRID 00003045
7/ Uniroyal Chemical, 1972, MRID 00002961
8/ Uniroyal Chemical, 1970, MRID 00025468

SORGHUM: Data were obtained on growing plants, grain, and fodder (plants after harvest) in Nebraska, South Dakota, Kansas, Missouri, and Texas.

SAMPLE	PHI (weeks)	RATE(s) (oz/cwt seed)	RESIDUE DISTRIBUTION ppm (as carboxin) <0.2	0.2-0.5	>0.5
READY-TO USE (FLOWABLE) [1]					
Whole plants	4-9	3,6	6	0	0
SOLUBLE CONCENTRATE-LIQUID [2]					
Whole plants	4-14	1.1,2.2	22	2	0
Fodder	14	1.1,2.2	8	0	0
Grain	7-14	1.1,2.2	6	0	0
WETTABLE POWDER/DUST [1,3]					
Whole plants	2-4	3,6	2	0	14*
Whole plants	4-11	3	8	6	0
Whole plants	4-11	6	7	1	6**

Residues declined with a half-life of 11 days [3]

[*] (0.6-10.8)
[**] (0.6-1.7)

[1] Uniroyal Chemical, 1969, MRID 00003045
[2] Uniroyal Chemical, 1975, MRID 00003054
[3] Uniroyal Chemical, 1970, MRID 00025468

Data on residues in plants are adequate for the currently registered uses of carboxin, and are consistent with existing tolerances.

5. Residues of Carboxin in Animals

Three lactating cows were administered phenyl-^{14}C-carboxin in the diet. Milk, urine, and feces were monitored daily for radioactivity, and after tendays of treatment the animals were sacrificed, and muscle, kidney, liver, and fat analyzed for radioactivity. Most of the radiolabel was excreted in the urine, the rate of excretion plateauing after the second day. Maximal radioactivity in the feces was reached in the first week. Trace radioactivity in milk plateaued after the first few days. Less than two percent of the ingested carboxin was detected in tissues at sacrifice. Residues were distributed as follows (Kennedy and Jenkins, 1971, MRID 00002945).

	TOTAL RESIDUE (PPB - EXPRESSED AS CARBOXIN)				
PPM ADMINISTERED	LIVER	KIDNEY	MUSCLE	FAT	MILK (MAXIMUM)
0.5	22	18	4	3	1
1.5	78	71	23	7	4
5.0	147	81	39	13	8

The feeding study adequately depicts the distribution of tagged residues in animals ingesting carboxin. However, the nature of the residue in food-producing animals is not known.

Data on residues in poultry and eggs have not been submitted to the Agency, however, the Agency is not requiring a poultry feeding study to support the seed treatment use of carboxin. The feeding study described above indicates no propensity for residues to accumulate in animal tissues, and data on residues in crops (see Residues in Plants) demonstrate the absence of detectable residues in poultry feed items.

B. LABELING REQUIREMENTS

Labels on all carboxin formulations are required to prohibit use of treated seed for food, feed, or oil purposes. A restriction on grazing livestock on treated areas for six weeks after planting should remain on products used on barley, corn, oats and wheat. Formulations used on cottonseed are required to bear a prohibition against grazing of livestock on treated areas and feeding hay grown from treated seed. The wettable powder formulation used on peanuts should continue to bear a restriction against grazing treated areas, but the current label restriction against feeding peanut hay (mature vines) to livestock is unnecessary because the established tolerance on peanut hay is adequate to cover seed treatment use.

C. SUMMARY OF DATA GAPS

Data demonstrating that the enforcement method is capable of determining the residue of concern in crops are required. Due to the SLN registrations for combined foliar and soil use, additional residue and metabolism studies on peanuts are required. If these studies show a higher residue level than that from seed treatment, residue and metabolism studies may be necessary on ruminants and poultry, since peanut meal, hulls, and soapstock are feed items.

VIII. ECOLOGICAL EFFECTS

A. Ecological Effects Profile
B. Ecological Effects Hazard Assessment
C. Summary of Data Gaps

A. ECOLOGICAL EFFECTS PROFILE

Scientifically sound data on the toxicity of technical or end-use carboxin to nontarget organisms are very limited. One study (Fink, 1974, MRID 00003139) showed that technical carboxin is practically nontoxic to mallard ducks, with an LC_{50} value greater than 4640 ppm.

A few studies were presented which demonstrate the phytotoxicity of technical carboxin. A study showed that five ounces of technical carboxin per one hundred pounds of seed (cwt) as a seed treatment had no effect on wheat or barley (Kratka, 1971, MRID 05003530). Another study demonstrated that cotton seedlings grown in a nutrient solution containing 40 ppm carboxin suffered severe growth reduction (Davis, 1971, MRID 05001204). In a third study, a 100 ppm foliar drench of carboxin had no effect on begonia growth (Harris, 1975, MRID 05003951).

The following EC_{10} values for seed treatments were demonstrated using a 34% flowable concentrate formulation:

Crop	Treatment	Reference
Cotton	8 oz./cwt	Uniroyal, 1972, MRID 00003125
Wheat	28 oz./cwt	Uniroyal, 1973, MRID 00003094
Barley	28 oz./cwt	Uniroyal, 1973, MRID 00003094
Peanuts	2.2 lb a.i./acre*	Uniroyal, 1977, MRID 00003236

* This is a foliar spray application.

There was no effect on wheat or oats from a seed treatment of 12 oz. a.i./cwt, the highest level tested for the 25% dust formulation. The EC_{10} for barley was 3-4 oz. a.i./cwt for the 25% dust (Uniroyal, 1977, MRID 00005548).

There was no effect from using the 75% wettable powder formulations as seed treatments on the following crops:

Crop	Treatment	Reference
Peanuts	6 oz. a.i./cwt	Uniroyal, 1973, MRID 00002910
Corn	3 oz. a.i./cwt	Uniroyal, 1971, MRID 00002951
Wheat	8 oz. a.i./cwt	Clark, 1971, MRID 05003675
Barley	4 oz. a.i./cwt	Clark, 1971, MRID 05003675

Foliar applications of the wettable powder formulation at the rate of eight to nine pounds a.i./acre had only a slight effect on peanuts (Uniroyal, 1971, MRID 00002859 and Uniroyal, 1975, MRID 00003149).

There was no effect to peanuts resulting from the application of three pounds a.i./acre of 4% granular carboxin when applied at the pegging stage (Uniroyal, 1973, MRID 00002861).

There was no effect to cotton following a seed treatment using an experimental 10% liquid formulation at a rate of 8 oz./cwt (Uniroyal, 1974, MRID 00003001).

B. ECOLOGICAL EFFECTS HAZARD ASSESSMENT

Insufficient information is available on the technical, or end-use products, or their degradates to evaluate the potential impacts from carboxin to nontarget fish and wildlife species.

Due to the scarcity of information, a detailed plant hazard assessment cannot be made at this time. However, there is some information concerning the effects of carboxin on crops on which it is used. Those crops (corn, cotton, peanuts, wheat, barley, and oats) suffer no ill effects from seed treatments at the recommended rates, although cotton displayed phytotoxic symptoms when subjected to a root drench at a higher rate. Begonia, the only ornamental tested, suffered no injury from a foliar drench.

All existing uses could expose nontarget fish and wildlife species to the parent compound or its degradates, carboxin sulfoxide and carboxin sulfone. However, in the absence of appropriate data the significance of the exposure cannot be addressed.

C. SUMMARY OF DATA GAPS

The following tests are needed to meet minimum fish and wildlife data requirements to support the registration of carboxin:

Avian single-dose oral LD_{50} test for either a wild waterfowl (preferably the mallard) or an upland game bird (preferably the bobwhite quail, other native

quail or the ring-necked pheasant). The species selected is to be the same as one of the two species selected for the avian dietary LC_{50} tests.

Avian dietary LC_{50} test for an upland game bird (preferably the bobwhite quail, other native quail, or the ringed-neck pheasant).

Fish acute LC_{50} test for one coldwater fish species, preferably the rainbow trout, and one warmwater species, preferably the bluegill.

Acute LC_{50} test for one species of freshwater invertebrate.

For the combined foliar and soil applications of carboxin, tests will need to be performed for the effect on seed germination, vegetative vigor, effects on algae, and aquatic macrophytes. These tests are not required for products registered soley for seed treatment.

Further data may be required depending upon the examination of the above data and adequate environmental chemistry data on the parent compound as well as its degradates.

IX. CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into two sections: (1) citations in numerical order that contributed information useful to the review of the chemical and are considered to be part of the data base supporting registrations under the standard, and (2) an alphabetical listing of all documents reviewed by the Agency. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD NUMERICAL BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Standard

MRID	CITATION
00002857	Uniroyal Chemical (1973) Enforcement Method for Vitavax®in Animal Tissue, Milk and Eggs. Method dated Sep 17, 1973. (Unpublished study received on unknown date under 3F1318; CDL:093547-D)
00002859	Uniroyal Chemical (1971) Reasoning in Support of the Petition: received Sep 27, 1972 under 3F1318; CDL:093547-O)
00002861	Uniroyal Chemical (1973) Vitavax® 10G: Peanuts: Phytotoxicity. (Unpublished study received Sep 28, 1976 under 400-130; CDL: 230405-N)
00002903	Uniroyal Chemical (1974) Residue Analysis of Peanut Hulls for Vitavax®. (Unpublished study received on unknown date under 4F1499; CDL:093979-C)
00002905	Uniroyal Chemical (1974) The Effects of EPA Tolerance Pesticides upon the Recovery of Vitavax® Residues from Peanuts. (Unpublished study received on unknown date under 4F1499; prepared in cooperation with Morse Laboratories, Inc.; CDL:093979-F)
00002910	Uniroyal Chemical (1973) Field Performance and Phytotoxicity Report. (Unpublished study received May 1, 1974 under 4F1499; CDL:094551-P)
00002935	Chin, W.T.; Dannals, L.E.; Kucharczyk, N. (1972) Environmental Fate Studies on Vitavax®: Status Report on PR 70-15. (Unpublished study received Mar 6, 1972 under 2F1191; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:093515-A)
00002938	Sisken, H.R. (1970) Determination of Residual Vitavax® in Meal and Oil from Cotton and Peanut Seed. (Unpublished study received Jul 28, 1972 under 0F0939; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091603-A)
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00002943	Kennedy, G. (1971) Report to Uniroyal Chemical, Division of Uniroyal, Inc.: Distribution and Excretion Study with Vitavax®in Albino Rats: IBT No. E9289. (Unpublished study received Oct 9, 1973 under 3F1318; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 092254-H)
00002944	Kennedy, G. (1971) Report to Uniroyal Chemical, Division of Uniroyal, Inc.: Characterization of 14C in Excreta of Rats Following Oral Administration of Vitavax®:IBT No. E9290. (Unpublished study received Oct 9, 1973 under 3F1318; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:092254-I)

MRID CITATION

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00002951 Uniroyal Chemical (1972) Field Performance Report. (Unpublished study including report, received Dec 23, 1972 under 3F1318; CDL:092253-F)

00002961 Uniroyal Chemical (1972) Residue Data: Vitavax®. (Unpublished study received on unknown date under 2F1191; prepared in cooperation with Morse Laboratories and Harris Laboratories; CDL:091003-A)

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00003030 Holsing, G.C. (1969) Final Report: Two-Year Dietary Administration--Dogs: Project No. 798-103. (Unpublished study received Jun 14, 1969 under 9G0819; prepared by Hazleton Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 091420-E)

00003031 Holsing, G.C. (1969) Final Report: 24-Month Dietary Administration--Albino Rats: Project No. 798-102. (Unpublished study received Jun 14, 1969 under 9G0819; prepared by Hazleton Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091420-F)

00003032 Holsing, G.C. (1968) Final Report: Three-Generation Reproduction Study--Rats: Project No. 798-104. (Unpublished study received Jun 14, 1969 under 9G0819; prepared by Hazleton Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL: 091420-G)

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MRID	CITATION
00003035	Holsing, G.C. (1968) Final Report: Acute Eye Irritation--Rabbits: Project No. 798-151. (Unpublished study received Jun 14, 1969 under 9G0819; prepared by Hazleton Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091420-L)
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00003296	Uniroyal Chemical (19??) Vitavax®: Chemical and Physical Properties of Vitavax® Technical. (Unpublished study received Sep 27, 1972 under 3F1318; CDL:093547-J)
00003231	Uniroyal Chemical (19??) Vitavax® Flowable Fungicide: Vitavax®-3F Fungicide: Basic Manufacturing Process. (Unpublisned study received Mar 20, 1979 under 400-80; CDL:098014-B)
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00003131 Uniroyal Chemical (1969?) Basic Vitavax® Toxicology Studies. (Unpublished study received May 16, 1973 under 400-107; CDL: 003284-R)

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00002946 Uniroyal Chemical (1969?) Uniroyal Supplemental Experimental Studies: Animal Residues. (Unpublished study received Oct 9, 1973 under 3F1318; CDL:092254-K)

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00003307 Uniroyal Chemical (1970?) Additional Vitavax® Toxicology. Summary of studies 091003-C through 091003-R. (Unpublished study received May 8, 1972 under 2F1191; CDL:091003-B)

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00002939 Uniroyal Chemical (1970) Vitavax® Handling Toxicity Studies. (Unpublished study received Oct 9, 1973 under 3F1318; CDL:092254-C)

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00002858 Uniroyal Chemical (1972) Stability of Vitavax® on Treated Seed (Grain and Corn). (Unpublished study received Sep 27, 1972 under 3F1318; CDL:093547-M)

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00005852	Uniroyal Chemical (1973) Residues in PPM: Corn: UNI-1088. (Unpublished study received Mar 28, 1977 under 400-107; prepared in cooperation with New York State Univ.--Oswego, Lake Ontario Environmental Laboratory and Morse Laboratories, Inc.; CDL: 238083-A)
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00002957	Uniroyal Chemical (1974) Toxicity of Vitavax® to Fish and Wildlife. (Unpublished study received Mar 21, 1974 under 400-113; CDL: 023366-F)

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00003017	Uniroyal Chemical (1976?) Soybeans: Vitavax®-200 Flowable Fungicide. (Unpublished study received Nov 14, 1978 under 400-12; CDL: 235936-D)
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00003165	Uniroyal Chemical (1977) [Residue Data: Vitavax®]. (Unpublished study received Apr 21, 1977 under unknown admin. no.; prepared in cooperation with Morse Laboratories, Inc.; CDL:229370-O)
00003357	Uniroyal Chemical (1977) Chemical and Physical Properties of Vitavax® Technical. (Unpublished study received Oct 11, 1978 under KS-78/20; submitted by ?; CDL:235366-A)
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00030107	Uniroyal Chemical (1977) Toxicology Vitavax HBM-25. Summary of studies 238226-B through 238286-F. (Unpublished study received Apr 25, 1979 under 400-136; CDL:238226-A)

MRID	CITATION
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00005863	Uniroyal Chemical (1977) Toxicology: Vitavax® 10G. Summary of studies 237329-F through 237329-I. (Unpublished study received Feb 6, 1979 under 400-EX-58; CDL:237329-E)
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00005548	Uniroyal Chemical (1977) Vitavax®-25DB: Phytotoxicity. (Unpublished study received Feb 28,1978 under 400-115; prepared in cooperation with the University of Idaho, Experiment Station; CDL:238076-D)
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MRID	CITATION
00020890	Uniroyal Chemical (1978) Vitavax®-25DB; Barley. (Unpublished study received Apr 25, 1979 under ND 79/8; prepared in cooperation with North Dakota State Univ. and Washington State Univ., Regional Cereal Disease Laboratory; CDL:238250-C)
00020888	Uniroyal Chemical (1978) Vitavax®-25DB; Oats. (Unpublished study received Apr 25, 1979 under ND 79/8; prepared in cooperation with North Dakota State Univ., South Dakota State Univ. and Univ. of Wisconsin, Dept. of Plant Pathology; CDL:238250-A)
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*U.S. GOVERNMENT PRINTING OFFICE: 1981 341-082/215 1-3