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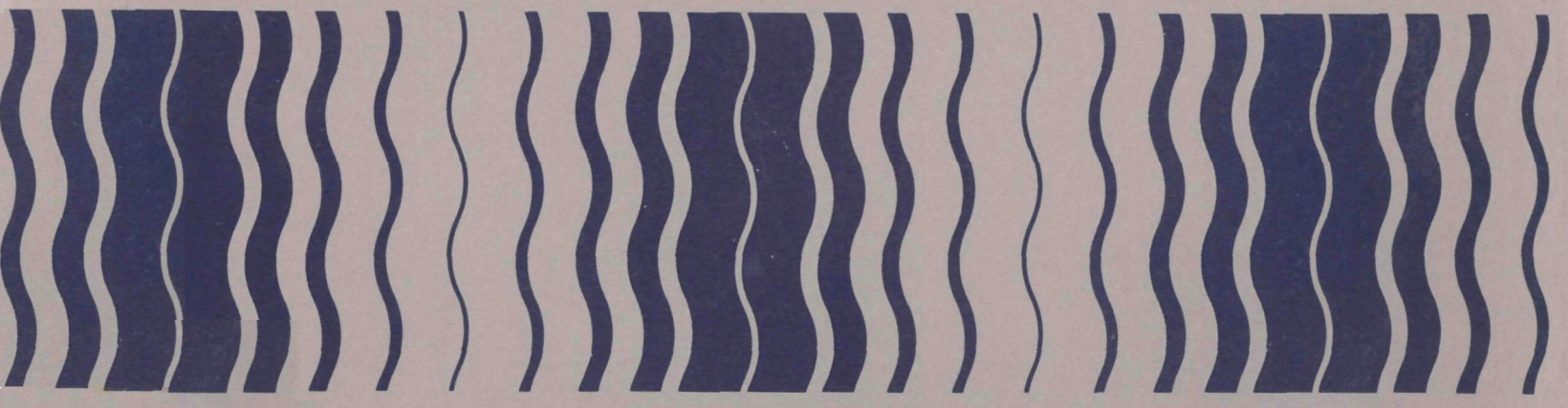
Pesticides

EPA

O-Ethyl O-(4-(methylthio) phenyl) S-propyl phosphorodithioate

Sulprofos

Pesticide Registration Standard



Sulprofos

Pesticide Registration Standard

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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:

"(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) 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. "Exclusive Use" and "Data Compensation" Under FIFRA Section 3(C)(1)(D)

FIFRA section 3(C)(1)(D)(i) provides special "exclusive use" protection for certain data concerning any pesticide product first registered after September 30, 1978, that contains an active ingredient not found in any previously registered product. (Bolstar®, with its new active ingredient sulprofos, is such a product.)

The statute provides that data submitted to support the original registration of such a product may not be considered by EPA to support the registration of another firm's product unless the original data submitter has consented in writing. This period of "exclusive use" lasts for 15 years after the initial registration. Mobay Chemical Corporation's registration for its Bolstar® product was issued on February 15, 1979. The Chapter III data charts contained within this standard indicate those data which are subject to this "exclusive use" provision.

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 <u>required</u> 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 those 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.

Chapter II: REGULATORY POSITION AND RATIONALE

A. Introduction
B. Description of Chemical
C. Regulatory Positon
D. Regulatory Rationale
E. Criteria for Registration under the Standard
F. Required Labeling
G. Tolerance Reassessment
H. New or Amended Registrations

A. Introduction

This chapter presents the Agency's regulatory position and rationale based upon an evaluation of all available data related to pesticidal products containing sulprofos (O-ethyl O-[4-(methylthio)phenyl] S-propyl phosphorodithioate) as their sole active ingredient. Following an abbreviated chemical description, this chapter presents the regulatory position and rationale, the criteria for registration/reregistration of sulprofos containing products, labeling considerations, and tolerance reassessment. A summary of all data requirements is contained within Chapter III. A discussion of the data upon which the Agency's regulatory postion is based is presented within disciplinary chapters IV through VIII.

B. Description of Chemical

Sulprofos (O-ethyl O-[4-(methylthio)phenyl] S-propyl phosphorodithioate) is currently conditionally registered with the U.S. Environmental Protection Agency as an insecticide/acaracide. At the time of publication of this Standard, cotton is the sole site of application. Sulprofos, in the literature, may be alternately identified as BAY NTN 9306, Helothion® and Bolstar®, the registered trade name under which sulprofos is currently marketed. The OPP Internal Control Number (EPA Shaughnessy Number) is 111501.

C. Regulatory Position

Sulprofos, as described within this Standard, may be registered for sale, distribution, reformulation and use within the United States and its territories. The Agency in preparing this Standard, has considered the scientific data obtained from the open literature through February 12, 1981, and those data submitted by the registrant up through the date of publication of this Standard. Based upon a review of these data, the Agency finds that sulprofos has neither met nor exceeded any of the risk criteria found within section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Agency has thus determined that sulprofos does not appear to cause

unreasonable adverse effects to either man or the environment when used in accordance with prescribed label directions and precautions. Currently registered sulprofos products may be reregistered subject to the conditions imposed under this chapter, and to the data requirements identified within Chapter III. New products, complying with the terms and conditions established for reregistration, may be registered under this standard.

D. Regulatory Rationale

A reasonably complete data base is available for registration support in relation to sulprofos. Those data which have yet to be developed, are princinpally confirmatory in nature. Sulprofos, as defined by available chronic test data, does not appear to induce oncogenicity, teratogenicity, mutagenicity or reproductive inhibition. Sufficient acute toxicity data are available to permit consideration for registration under those parameters provided within paragraphs E.1.b. and E.2.b. of this chapter.

Although certain items of data remian outstanding, the Agency has concluded to register or reregister sulprofos containing products. The Agency provides as a basis for this decision the following:

1. No adverse effects data of regulatory concern have been revealed in the review of those studies made available to the Agency. The Agency, therefore, has concluded that the known risks, as mitigated by product labeling, are of such a nature as to warrant no immediate adverse regulatory action.

2. No confirmed pesticide poisioning or environmental effect incidents have been reported to the Agency.

3. The Agency's policy, in keeping with the intent of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is to neither routinely cancel existing product registrations nor deny new registrations for products for which incomplete data bases may exist. (See sections 3(c)(2)(B) and 3(c)(7) of the FIFRA.) The Agency believes that publication of this Standard permits not only the identification of data needs, but also allows for the upgrading of labels during the period in which the required data are being generated. Upon receipt and review of outstanding data, the Agency will reassess the registrability of each given chemical.

E. Criteria for Registration Under The Standard

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

- Contain O-Ethyl O-[4-(methylthio)phenyl] S-propyl phosphorodithioate as the sole active ingredient (herein defined as including products containing up to and including 15% petroleum distillate),

- bear required labeling,

- conform to the product composition standard, acute toxicity limits, and use pattern requirements as specified in part 1.a., b., and c., and 2.a., b., and c., respectively.

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

1. Manufacturing-Use Products

a. Product Composition Standard

To be elegible for registration/reregistration under this standard, manufacturing-use products must contain sulprofos as their sole active ingredient. Such formulations may contain percentages of active ingredient up to and including 87.0%. Each formulation proposed for registration must be fully described within an appropriate certification of limits.

b. Acute Toxicity Limits

Due to the intended use of manufacturing-use sulprofos products, there are no acute toxicity limits.

c. Use Patterns

To be eligible for registration/reregistration under this standard, manufacturing-use products must bear labeling limiting use to the formulation of insecticide/acaracide end-use products intended for application to cotton.

2. End-use Products

a. Product Composition Standard

Any end-use product containing 64% sulprofos in combination with 0 to 15% petroleum distillate will be considered under this Standard. Each proposed formulation must be fully described within an appropriate certification of limits.

b. Acute Toxicity Limit

The Agency, given the single agricultural site of application, will consider for registration end-use products of any toxicity category. This acceptance, however, is predicated upon label incorporation of appropriate hazard warnings, precautionary, and use restriction statements as may be required. The Agency will, therefore, consider the registration of any emulsifiable concentrate formulation in the following categories:

	Toxicity Category			
	I	II	III	IV
Acute oral Toxicity	Yes	Yes	Yes	Yes
Acute Dermal Toxicity	Yes	Yes	Yes	Yes
Acute Inhalation Toxicity	Yes	Yes	Yes	Yes
Primary Dermal Irritation	Yes	Yes	Yes	Yes

c. Use Pattern

To be considered under this Standard, end-use products must bear directions for use as an insecticide/acaricide intended for either ground or aerial application to cotton.

F. Required Labeling

All manufacturing-use and end-use sulprofos products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package which accompanies this Standard contains specific information regarding label requirements.

1. Manufacturing-Use Products

All manufacturing-use sulprofos products must bear a label statement which provides that the product may be used only in the formulation of insecticide/acaracide products approved by the United States Envionmental Protection Agency.

2. End-use Products

a. Human hazard precautionary statements

The human hazard precautionary statements are to be segregated according to the various routes of exposure, with the routes of greatest hazard being listed first. The statements will be consistant with those provided by the Guidance Package.

b. Environmental hazard statements

The Agency believes that end use product application must be restricted to trained applicators because of the apparent high toxicity of sulprofos to fish and wildlife. It is the Agency's belief that such a restriction will minimize the potential for over-application, and application to nontarget sites. End use sulprofos labeling, therefore, must bear the following statement:

"RESTRICTED USE PESTICIDE"
"For retail sale and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification"

The "Restricted Use" classification of sulprofos will be reevaluated upon submission and review of those pertinent studies identified as data gaps within Chapter III of this Standard.

In conjunction with the "Restricted Use" classification, the following environmental hazard statements pertinent to the potential effect of sulprofos application on fish and wildlife must appear on end-use product labeling.

"This pesticide is toxic to fish and wildlife. Use with care when applying in areas frequented by wildlife or adjacent to any body of water. Do not apply directly to water. Do not apply when weather conditions favor run-off or drift from target areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

The Agency has additionally noted that sulprofos can pose a threat to honey bees. In this regard, end-use sulprofos labeling must bear the following environmental hazard statement:

"This product is toxic to bees exposed to direct treatment or residues on crops or weeds. Do not apply this product or allow it to drift to crops or weeds on which bees are actively foraging."

G. Tolerance Reassessment

Sulprofos has been granted those tolerances requisite for application to cotton. (See 43 FR 32132 of July 25, 1978). Tolerances of 0.01 ppm have been established for the fat, meat and meat by-products of cattle, goats, hogs, horses poultry and sheep. A 0.001 ppm tolerance level has been established for milk and eggs, and a 0.5 ppm level for cottonseed. Since toxicological data considered in support of those tolerances established as of July 25, 1978, are

identical to those data reviewed under this Standard, the Agency does not believe that there exists any reasonable cause to reassess current sulprofos tolerances. In similar fashion, the Agency has noted no additional residue chemistry, international tolerance, or similar considerations which might give cause for a reassessemt of existing tolerances.

Based upon the the 10 ppm no observed effect level (NOEL) derived from the two-year dog-feeding study discussed within Chapter VI of this Standard, the acceptable daily intake (ADI) for man has been calculated to be 0.025 mg/kg body weight per day. The established tolerances theoretically represent 0.32 percent of the acceptable daily intake (ADI). The theoretical maximal residue contribution (TMRC) in the human diet from these tolerances is 0.0048 mg/day. The Agency, upon consideration of all available toxicity data, has concluded that a sulprofos TMRC of 0.0048 mg/day would pose no risk to human health.

The Agency has, however, noted in its review of rotational crop residue data that sulprofos residues can occur in crops planted in excess of one year following the last application (see Chapter V). In light of the proven potential for rotational residues, the Agency has determined that sufficient cause exists to impose, in the absence of petitions for rotational crop tolerances, a rotational crop restriction. The following statement must appear upon all end-use sulprofos labeling:

"Rotational crops may not be grown in fields
treated with this product."

The registrant(s) may, at their discretion, amend the above rotational crop restriction by providing a six month rotational restriction specific to potatoes and cucumbers and a 60 day rotational restriction specific to turnips and peas. A complete restriction for all other crops must, however, accompany any statement pertaining to potatoes, cucumbers, turnips and/or peas. The registrant(s), further, retain options for the amendmending or removal of the rotational crop restriction. The registrant(s) may submit environmental fate data to support a rotation interval which does not result in a pesticide residue in the rotated crop. Alternatively, the registrant(s) may submit a petition for tolerance for the nontarget crop or request an exemption from a tolerance.

An additional Agency concern regarding tolerances involves current labeling permitting the application of tank mixes of sulprofos and Guthion to cotton up to 21 or 14 days before harvest. Although it is not Agency policy to customarily address tank mixes within single active Standards, the appearance of the tank mix instructions only upon Bolstar® 6 labeling necessitates the current incorporation of a label restriction. As both compounds are cholinesterase inhibitors, samples bearing residues of both compounds at their respective tolerance levels (0.5 ppm) would be in violation of 40 CFR 180.3(e)(1). The Agency believes, in view of data indicating that Guthion

residues applied 14 days before harvest would not be significant (<0.05 ppm), has concluded that the tank mix, if not followed by subsequent applications of Guthion, would not be in violation of 180.3(e)(1). Since current Guthion labeling, however, would permit additional applications (up to one day before harvest), it is the Agency's judgment that the tank mix recommendation must bear a restriction prohibiting any additional application of Guthion within 14 days of harvest.

H. New and Amended Registrations Under This Standard

Principal among the goals of the Registration Standards process is not only the reregistration of currently registered pesticide chemicals, but also the creation of a mechanism for the registration of new and added uses of a chemical. Although sulprofos bears current registration only for use on cotton, it may be anticipated that new sites of application will be sought. Being a broad spectrum organophosphate insecticide/acaracide, it would be virtually impossible to anticipate future registration actions with any degree of certainty. It is, however, possible to define the general applicability of this Standard.

The Agency in its review of the current data base has determined that sulprofos does not appear to present any human chronic toxicity hazard. The Agency can not make a categorical statement with respect to chronic hazard until such time as certain mutagenicity and teratogenicity studies, identified in Chapter III, are submitted and reviewed. Assuming these studies produce negative findings, the Agency will adopt the results and conclusions of this Standard for all future registration actions. Additional chronic data will not be required except under those circumstances in which major alterations in use pattern and formulation might be sought. An example of such an alteration would be the use of sulprofos in an aerosol or pressurized spray formulation intended for indoor use. Should such a registration be sought, the Agency would require the submission of an acceptable subchronic inhalation toxicity study as described under Guideline section 163.82-4. The Agency might also seek chronic toxicity data should the technical synthesis process be altered to permit the introduction of additional unintentional ingredients or should the ratio of those unintentional ingredients currently known to the Agency be radically altered. Similarly, the addition of inert ingredients into the manufacturing-use product(s) might necessitate the submission of additional data.

In similar fashion, the Agency will seek to apply the acute toxicity data presented within this Standard in as broad a fashion as may be deemed scientifically justifiable. With regard to manufacturing-use sulprofos, the potential range of formulations is limited. The Agency is not in a position to ascertain whether or not increasing the percentage of parent sulprofos, currently 87.0 percent, would alter a given toxicity category. Similarly, any reduction from the current 87.0 percent level may or may not entail the addition of unintentional ingredients. As a consequence, no specific range may

be established under this standard. This does not, however, preclude Agency use of the current acute toxicity data base. The Agency will review the discussion on formation of unintentional ingredients as well as the delaration and certification of ingredient limits for any new manufacturing-use product(s) and, from these data, make a determination as to the necessity for additional acute studies.

In relation to end use sulprofos products, the current data base was established as a result of tests conducted upon a 64 percent sulprofos formulation containing 15 percent petroleum distillates. As discussed within Chater VI of this Standard, the acute toxicity of the end-use product is equal to or less than that of the manufacturing-use product for each criteria except eye irritation. The Agency will, therefore, accept, without the submission of additional acute toxicity data, the registration of any emulsifiable concentrate end use product having 64 percent or less sulprofos as its sole active ingredient. This acceptance is based on Agency review of the product identity and disclosure of ingredients statement accompanying each application for registration. In only those cases where Agency review reveals the presence of an inert ingredient of known or suspected acute toxicological significance will additional acute toxicity data be requested. The eye irritancy is thought to be related to the petroleum distillate. Petroleum distillates are additionally known to manifest other acute toxicity symptoms. The Agency has, therefore, established a current data applicability limit to products containing 15 percent or less petroleum distillates. Registrants wishing to register an end-use formulation containing a significantly lessened percentage of active ingredient may rely upon the current data base. It must be noted, however, that in the absence of additional acute toxicity data, product labeling must bear those precautionary statements indicated by the current data base.

The current Environmental Fate data base, like that for toxicology, is reasonably complete. There remains some question with regard to the fate of sulprofos when applied to muck soil, and in relation to the movement of sulprofos and certain of its degradation products in the environment. A sufficient data base is, however, available to support certain additonal patterns of use. The Agency will consider, upon submission of acceptable adsorption/desorption data and applicable crop specific residue chemistry data (see Chapters V and VII), the registration of emulsifiable concentrate formulations falling within the concentration range described above for all field and vegetable crops. The general applicability of the data base is limited, in part, as follows: (1) crops grown in muck soils will not be registrable until such time as the existing muck soil dissipation data may be clarified or new data submitted, (2) as some question remains as to the movement of sulprofos and certain of its degradation products, the Agency will require a sandy soil use restriction, and (3) the addition of leguminous crops will require a reinvestigation of potential breaks in the nitrogen fixation cycle.

In addition to field and vegetable crops, the existing data base is broadly applicable to other potential sites of application. Only those studies unique to the newly proposed site need be pursued. Forest use, as an example, would require those additional items of data identified under section 163.62-10(d). Greenhouse use, as another example, would require the generation of both volatility and adsorption data. In all cases, the Agency will strive to apply the existing data base, requiring only those studies which are unique to a given use pattern. To ascertain the need for additonal data, the data base presented by this standard may be compared to the site specific requirements outlined under Guideline section 163.62-6.

Unlike the data bases for either toxicology or environmental fate, the ecological effects data base remains somewhat incomplete. The available data strongly suggests that sulprofos and/or its degradation products is acutely toxic to avian and aquatic species. The Agency must, therefore, exercise caution in extending the current data base in support of additonal sites of application. Until such time as the Agency may receive and evaluate the adsorption/desorption and avian field studies identified as data gaps in Chapter III of this Standard, the Agency must not attempt to identify additional registerable sites. The Agency will, however, entertain applications for new or amended registration and on a case-by-case basis apply the existing data base for added field and vegetable crops. The Agency does not believe that the current data base would permit the extension of registration beyond certain, field and vegetable crop sites of application. Aquatic, forest, and similar sites of fish and wildlife concern are not supportable under the current data base.

CHAPTER III: SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

A. Introduction
B. Table A - Generic Data Requirements
C. Table B - Product Specific Manufacturing Use Products Data Requirements
D. Table C - Product Specific End-Use Product Data Requirements

A. Introduction

Applicants for registration of manufacturing-use and end-use sulprofos 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.

Listed before each requirement is the Proposed Guidelines section 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 requiring the test is provided in the Guidelines. A discussion of why data additional to that already submitted are necessary, or why data normally required are not necessary for this chemical, is 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.

Table A: Sulprofos
Generic Data Requirements: Environmental Fate (Chapter V)

Guidelines Citation	Name of Test	Are Data Required?	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	yes	Tech. or Radiolabeled Analytical Gr.	yes	GS0076-034	no
163.62-7(c)	Photodegradation	yes	Tech. or Radiolabeled Analytical Gr.	yes	GS0076-025,-026, -098	no
163.62-8(b)	Aerobic Soil Metabolism	yes	Tech. or Radiolabeled Analytical Gr.	yes	GS0076-167	no
163.62-8(c)	Anaerobic Soil metabolism	yes	Tech. or Radiolabeled Analytical Gr.	yes	GS0076-034	no
	Microbial Metabolism:					
	(2) Effects of Microbes on Pesticides	reserved[2/]	Tech. or Radiolabeled Analytical Gr.	-	GS0076-143	—
	(3) Effects of Pesticides on Microbes	reserved[2/]	Tech. or Radiolabeled Analytical Gr.	-	GS0076-108,-144, -145,-177	—[1/]
	Activated sludge metabolism	reserved[2/]	Tech. or Radiolabeled Analytical Gr.	-	-	-

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ As discussed within Chapter V, the available data indicate that sulprofos and/or its degradation products may cause a break in the nitrogen cycle. Although the Agency does not believe it necessary to identify a data gap for cotton use, the Agency may require additional data should registration be sought for sulprofos use on crops for which nitrogen fixation is agriculturally important.

2/ The requirement for submission of these data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.

Table A: Sulprofos
Generic Data Requirements: Environmental Fate (Chapter V)

Guidelines Citation	Name of Test	Are Data Required?	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?
163.62-9(b)	Leaching	yes	Tech. or Radiolabeled Analytical Gr.	yes	GS0076-024,-025	no
163.62-9(d)	Adsorption/Desorption	yes	Tech. or Radiolabeled Analytical Gr.	no	-	yes/8 mo.[1/]
163.62-10(b)	Terrestrial Field Dissipation:					
	(1) Field & Vegetable Crops	yes	Emulsifiable Concentrate	yes	GS-0076,016,-017, -018,-019,-057,-058, -059,-060,-061,-062, -063,-064,-065,-066, -067,-068,-075,-084, -151,-156,-158,-167	no[2/]
163.62-10(f)	Combination and tank mix field dissipation		reserved[3/]	-	-	-

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ Adsorption/desorption coefficients must be provided for all degradation products shown to comprise 10 percent or more of applied activity.

2/ The Agency, in reviewing available muck soil dissipation data, has noted inconsistencies in the findings. The Agency does not, however, deem the absence of valid muck soil dissipation data to be critical to the cotton pattern of use for which sulprofos is currently registered. Should new uses, involving crops grown in muck soil, be pursued, additional dissipation data will be requested.

3/ Not applicable in single active ingredient Standards.

Table A: Sulprofos
Generic Data Requirements: Environmental Fate (Chapter V)

Guidelines Citation	Name of Test	Are Data Required?	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?
163.62-11(b)	Accumulation in Rotational Crops	yes	Radiolabeled Analytical Gr. Followed by Formulation	partial	GS0076-001,-002, -003,-004,-005,-006, -007,-008,-009,-010, -011,-012,-013,-014, -015,-056,-173	no[1/]
163.62-11(d)	Fish Accumulation	yes	Tech. or Radiolabeled Analytical Gr.	yes	GS0076-139	no

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ Removal of rotation crop restriction requires one of the following:

a) Environmental fate data to support a rotation interval which does not result in a pesticide residue in the rotated crop;

b) A tolerance for the nontarget crop;

c) An exemption from a tolerance.

Table A: Sulprofos
Generic Data Requirements: Toxicology (Chapter VI)

Guidelines Citation	Name of Test	Are Data Required?	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	yes	Each Product or Substantially Similar Product	yes	GS0027-125,-126, -130,-131,-132,-133, -134,-135,-136,-137	no
163.81-2	Acute Dermal Toxicity	yes	Ea. Prod. or Substan. Sim. Prod.	yes	GS0076-122	no
163.81-3	Acute Inhalation Toxicity	yes	Ea. Prod. or Substan. Sim. Prod.	yes	GS0076-102	no
163.81-4	Primary Eye Irritation	yes	Ea. Prod. or Substan. Sim. Prod.	yes	GS0076-092	no
163.81-5	Primary Dermal Irritation	yes	Ea. Prod. or Substan. Sim. Prod.	yes	GS0076-092	no
163.81-6	Dermal Sensitization	yes	Ea. Prod. or Substan. Sim. Prod.	yes	GS0076-118	no
163.81-7	Acute Delayed Neurotoxicity	yes	Ea. Prod. or Substan. Sim. Prod.	yes	GS0076-181	no
163.82-1	Subchronic oral Toxicity	yes	Tech. Grade of A.I. .	yes	GS0076-091,-109, -110	no[1/]

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ As noted within Chapter VI of this Standard, the subchronic oral toxicity data submitted for Agency review do not fully comply with Guideline requirements. As provided under section 163.82-1(c)(6)(ii), tests conducted with nonrodents must be of a six month duration. The available subchronic dog feeding study was conducted for a period of only 90 days and, hence, must be judged as supplementary data only. The availability of negative chronic feeding studies obviates the necessity for additional short-term testing. The Agency therefore, has concluded that additional subchronic oral toxicity studies need not be submitted.

Table A: Sulprofos
Generic Data Requirements: Toxicology (Chapter VI)

Guidelines Citation	Name of Test	Are Data Required?	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?
163.82-2	Subchronic 21-Day Dermal Toxicity	yes[1/]	-	no	-	no
163.82-4	Subchronic Inhalation Toxicity	yes	Tech. Grade of A.I.	partial	GS0076-103	no[2/]
163.82-5	Subchronic Neurotoxicity	no[3/]	-	-	-	no

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ Although customarily required, the Agency is prepared to waive the data requirement for a subchronic 21-day dermal toxicity test on the manufacturing-use product. This waiver is based upon the absence of observable chronic effects in any of the chronic studies which have been made available for Agency review, and upon the availability of a subchronic 21-day dermal toxicity test conducted utilizing the 64% end-use product. This latter study provides no evidence of any chronic effect ensuing from repeated dermal exposure.

2/ As noted within Chapter VI, the available subchronic inhalation study fails to meet the duration requirement established under section 163.82-4(c)(5). The Agency, however, is prepared to waive the submission of additional subchronic inhalation toxicity data. The Agency has determined that although the pattern of chemical use will lead to some inhalational exposure to spray mist, such exposure will be limited. The Agency additionally finds no pattern of chronic effects have been established in response to the review of other available chronic data.

3/ The Agency, based upon its review of available acute delayed neurotoxicity data, finds that the criteria established under 163.82-5(a)(1) and (2) have not been met. Due to the negative findings of the acute delayed neurotoxicity study in relation to both neuropathy and delayed neurotoxicity, the Agency will not impose a subchronic neurotoxicity data requirement.

Table A: Sulprofos
Generic Data Requirements: Toxicology (Chapter VI)

Guidelines Citation	Name of Test	Are Data Required?	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 Study	yes	Technical Grade of Active Ingredient	yes	GS0076-114	no
163.83-2	Oncogenicity	yes	Tech. Grade of A.I.	yes	GS0076-115,-117	no
163.83-3	Teratogenicity	yes	Tech. Grade of A.I.	partial	GS0076-141	yes[1/]
163.83-4	Reproduction	yes	Tech. Grade of A.I.	partial	GS0076-095	no
-	Mutagenicity	yes	Tech. Grade of A.I.	partial[2/]	GS-0076-140	yes/14 mo.[2/]
163.85-1	Metabolism	yes	Tech. Grade of A.I.	yes	GS-0076-032	no

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ As provided under section 163.83-3(b)(2) teratogenicity testing "shall be performed in at least two mammalian species. The rat, mouse, hamster, or rabbit is acceptable. Other species may be used if adequate justification is supplied. One species should be the same as the species used in the reproduction study (section 163.83-4)." The above-cited teratogenicity study, while acceptable, must be supplemented by a confirmatory second study. As the submitted study investigated the teratogenic potential of sulprofos in relation to rabbits, the Agency would prefer that the outstanding study be conducted utilizing the laboratory rat.

2/ The following studies represent only the minimum requirements for data on the potential heritable effects of sulprofos:

1. A mammalian in-vitro point mutation test.
2. A sensitive sub-mammalian point mutation test. (Bacteria, fungi, insect).
3. A primary DNA damage test (i.e. sister chromatid exchange or unscheduled DNA synthesis).
4. A mammalian in-vitro cytogenetics test. If this test suggests a positive result, a dominant lethal or heritable translocation test may be required.

After results from these test systems and other toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

Although the Agency's mutagenic testing requirements are not final, the standards for these tests should be based on the principles set forth in 43 FR 37388. Protocols and choices of test systems should be accompanied by a scientific rationale. Substitutions of test systems for those listed above will be considered after discussion with the Agency.

The requirements should be considered an interim guide and not final Agency policy. However, the Agency does consider the above testing scheme to be a reasonable minimum requirement.

As the submitted study involved a negative dominant lethal assay, the Agency will consider the requirement for a mammalian in-vitro cytogenetics test to have been fulfilled.

Table A: Sulprofos
Generic Data Requirements: Residue - Chemistry (Chapter VII)

Guidelines Citation	Name of Test	Are Data Required?	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	yes	-	yes	GS0076-034	no
-	Metabolism in Animals	yes	-	yes	GS0076,-078,-083, -093,-099,-168	no
-	Analytical Methods	yes	-	yes	GS0076-022,-039, -072,-074,-076,-159, -169,-172,-174,-175	no
-	Residue Data: Crop	yes	-	yes	GS0076-027,-028, -036,-044,-045,-046, -047,-048,-049,-050, -051,-052,-053,-054, -055,-077,-096,-147, -148,-155,-162,-170, -171,-176,-182	no
-	Residue Data: Meat, Milk and Eggs	yes	-	yes	GS0076-037,-038, -040,-041,-043,-146, -155	no
-	Storage Stability	yes	-	yes	GS0076-020,-021, -023,-166	no

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

Table A: Sulprofos
Generic Data Requirements: Ecological Effects (Chapter VIII)

Guidelines Citation	Name of Test	Are Data Required?	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}	yes	Tech.	yes	GS0076-081,-119	no
163.71-2	Avian Dietary LC_{50}	yes	Tech.	yes	GS0076-120	no
163.71-3	Mammalian Acute Toxicity	no[1/]	-	-	-	no
163.71-4	Avian Reproduction	yes	Tech.	yes	GS0076-082,-185	no
163.71-5	Simulated and Actual Field Testing for Mammals & Birds	yes	Tech.	no	-	yes/16 mo.[2/]
163.72-1	Fish Acute LC_{50}	Reserved[3/]	Tech.	partial	GS0076-138,-163	yes/16 mo.

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ The Agency shall waive the requirement for the acute testing of mamalian species indigenous to potential sites of application. This waiver is predicated upon acceptable toxicity ranges established as a result of those mamalian studies conducted in compliance with human and domestic animal toxicity guideline requirements.

2/ Field testing for avian species are required. The eight-day, dietary LC_{50} to bobwhite quail has been established at 99 ppm. This LC_{50} falls below Agency calculated worst-case feed residue levels.

3/ Although the submitted fish acute LC_{50} studies have provided supplemental data useful in establishing the acute toxicity of sulprofos to fish, the data have been judged inadequate due to insufficient quantities of solubilized test substance. The Agency additionally retains a concern that certain degradation products, principally sulfoxide, may possess greater solubility than the parent compound and hence, may move more readily into aquatic environments. The Agency will require, within the time interval noted above, fish acute LC_{50} studies on parent sulprofos. The Agency will, however, reserve, pending the development of those adsorption/desorption data requested under the Environmental Fate portion of this Chapter, a determination as to any additional acute toxicity requirements related to the degradation products.

Table A: Sulprofos
Generic Data Requirements: Ecological Effects (Chapter VIII)

Guidelines Citation	Name of Test	Are Data Required?	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?
163.72-2	Acute Toxicity to Aquatic Invertebrates	yes	Tech.	yes	GS0076-160,-164	no
163.72-4	Embryolarvae & Life-cycle Studies of Fish & Aquatic Invertebrates	Reserved[1/]	-	-	-	reserved[1/]
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	Reserved[1/]	-	-	-	reserved[1/]
163.122-1	Vegetative Vigor	yes	Tech.	no	-	yes/16 mo.
163.122-1	Seed Germination	yes	Tech.	no	-	yes/16 mo.
163.122-2	Aquatic Macrophyte	yes	Tech.	no	-	yes/16 mo.
163.122-2	Algae	yes	Tech.	no	-	yes/16 mo.

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements. A numerical bibliography (MRID) is provided at the end of this Standard.

1/ The Agency will reserve a determination as to the necessity of these studies pending receipt and evaluation of the adsorption/desorption data requested elsewhere within this chapter.

Table B: Sulprofos

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

Guidelines Citation	Name of Test	Are Data Required?	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	yes	Each Product	yes	-	yes[1/]
163.61-4	Description of Manufacturing Process	yes	Each Product	yes	-	yes[1/]
163.61-5	Discussion on Formation of Unintentional Ingredients	yes	Each Product	yes	-	yes[1/]
163.61-6	Declaration & Certification of Ingredients Limits	yes	Each Product	no	-	yes[1/]
163.61-7	Product Analytical Methods & Data	yes	Each Product	yes	GS0076-149	no
163.61-8(c)(1)	Color	yes	Technical Grade of Active Ingredient	yes	-	yes[1/]
163.61-8(c)(2)	Odor	yes	Tech. Grade of A.I.	yes	-	yes[1/]
163.61-8(c)(3)	Melting Point	yes	Tech. Grade of A.I.	yes	-	yes[1/]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography (MRID) is provided at the end of this Standard.

1/ These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirements have been partially or completely fulfiled for some products, no references are given. Except for 163.61-7, these requirements must be filled at the time of registration or reregistration.

Table B: Sulprofos
Product Specific Manufacturing Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Are Data Required?	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?
163.61-8(c)(4)	Solubility	yes	Tech. Grade of Active Ingredient	yes	-	yes[1/]
163.61-8(c)(5)	Stability	yes	Tech. Grade of A.I.	yes	-	yes[1/]
163.61-8(c)(6)	Octanol/Water Partition Coefficient	yes	Tech. Grade of A.I.	no	-	yes[1/]
163.61-8(c)(7)	Physical State	yes	Tech. Grade of A.I.	yes	-	yes[1/]
163.61-8(c)(8)	Specific Gravity	yes	Tech. Grade of A.I.	yes	-	yes[1/]
163.61-8(c)(9)	Boiling Point	no	Tech. Grade of A.I.	yes	-	yes[1/]
163.61-8(c)(10)	Vapor Pressure	yes	Tech. Grade of A.I.	yes	-	yes[1/]
163.61-8(c)(11)	pH	yes	Tech. Grade of A.I.	no	-	yes[1/]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography (MRID) is provided at the end of this Standard.

1/ 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. Except for 163.61-7, these requirements must be filled at the time of registration or reregistration.

Table B: Sulprofos
Product Specific Manufacturing Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Are Data Required?	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?
163.61-8(c)(12)	Storage Stability	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(13)	Flammability	yes	Each Product	no	-	yes/6 mo.[1/]
163.61-8(c)(14)	Oxidizing/Reducing Action	yes	Each Product	no	-	yes/6 mo.[1/]
163.61-8(c)(15)	Explosiveness	yes	Each Product	no	-	yes/6 mo.[1/]
163.61-8(c)(16)	Miscibility	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(17)	Viscosity Coefficient	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(18)	Corrosiveness	yes	Each Product	no	-	yes/6 mo.[1/]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography (MRID) is provided at the end of this Standard.

1/ 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. Except for 163.61-7, these requirements must be filled at the time of registration or reregistration.

Table C: Sulprofos

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

Guidelines Citation	Name of Test	Are Data Required?	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	yes	Each Product	yes	-	yes[1/]
163.61-4	Description of Manufacturing Process	yes	Each Product	yes	-	yes[1/]
163.61-5	Discussion on Formation of Unintentional Ingredients	yes	Each Product	no	-	yes[1/]
163.61-6	Declaration & Certification of Ingredients Limits	yes	Each Product	no	-	yes[1/]
163.61-7	Product Analytical Methods & Data	yes	Each Product	yes	GS0076-150	no

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography (MRID) is provided at the end of this Standard.

1/ 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. Except for 163.61-7, these requirements must be filled at the time of registration or reregistration.

Table C: Sulprofos
Product Specific End-Use Product Data Requirements: Product Chemistry (See Chapter IV)

Guidelines Citation	Name of Test	Are Data Required?	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?
163.61-8(c)(1)	Color	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(2)	Odor	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(7)	Physical State	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(8)	Specific Gravity	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(11)	pH	yes	Each Product	no	-	yes[1/]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography (MRID) is provided at the end of this Standard.

1/ 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. Except for 163.61-7, these requirements must be filled at the time of registration or reregistration.

Table C: Sulprofos

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

Guidelines Citation	Name of Test	Are Data Required?	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?
163.61-8(c)(12)	Storage Stability	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(13)	Flammability	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(14)	Oxidizing/Reducing Action	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(15)	Explosiveness	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(16)	Miscibility	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(17)	Viscosity Coefficient	yes	Each Product	yes	-	yes[1/]
163.61-8(c)(18)	Corrosiveness	yes	Each Product	no	-	yes[1/]

These data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography (MRID) is provided at the end of this Standard.

1/ 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. Except for 163.61-7, these requirements must be filled at the time of registration or reregistration.

Table C: Sulprofos
Product Specific End-Use Product Data Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Are Data Required?	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	yes	Each Product or Substantially Similar Product	yes[1/]	GS0076-127	no
163.81-2	Acute Dermal Toxicity	yes	Ea. Prod. or Substan. Sim. Prod.	yes[1/]	GS0076-123	no
163.81-3	Acute Inhalation Toxicity	yes	Ea. Prod. or Substan. Sim. Prod.	yes[1/]	GS0076-124	no
163.81-4	Primary Eye Irritation	yes	Ea. Prod. or Substan. Sim. Prod.	yes[1/]	GS0076-129	no
163.81-5	Primary Dermal Irritation	yes	Ea. Prod. or Substan. Sim. Prod.	yes[1/]	GS0076-128	no
163.81-6	Dermal Sensitization	yes	Ea. Prod. or Substan. Sim. Prod.	no	-	yes/9 mo.

All data requirements are current as of August, 1981. Refer to the guidance package for updated requirements.
A numerical bibliography is provided at the end of this Standard.

1/ The available data are adequate in support of end-use products, having a composition range of 64% or less sulprofos in combination with 0 to 15% petroleum distillates as the sole active ingredients.

IV. PRODUCT CHEMISTRY

A. Product Chemistry - Manufacturing-Use Products
B. Product Chemistry - End Use Products

A. Product Chemistry - Manufacturing-Use Sulprofos

1. Manufacturing Process

Sulprofos, O-ethyl O-[4-(methylthio)phenyl] S-propyl phosphorodithioate, is an insecticidal compound originated by the parent company Bayer AG, Leverkusen, West Germany with development by Chemagro Agricultural Division of Mobay Chemical Corporation. At the time of development of this Standard, only a single manufacturing use (technical) product has been registered with the Agency. A complete description of the process by which technical sulprofos is manufactured has been provided to the Agency (Mobay Chemical Corporation 1975, MRID GS0076-149). Details of this process, however, are considered by the Agency to be of trade secret information and, hence, will not be provided within this standard. Related synthesis descriptions (for O-ethyl-S-propyl-dithiophosphoric acid phenyl or naphthyl esters) may be found under United States Patent 3,947,529 (Kishino et al., 1974, MRID GS0076-104).

2. Unintentional Ingredients

Technical sulprofos is approximately 90% pure. Twenty-one impurities have been isolated and are known to the Agency. Like the manufacturing process, however, the characterization of these impurities is considered trade secret. It may be stated that the majority of these impurities are related to organophosphate compounds. Three components remain unidentified, but, in aggregate, account for only 0.2% of the technical formulation. No single compound comprises more than 1.5% of the total formulation and only seven comprise more than 0.5% of the technical material (Patel, 1976, MRID GS0076-165). The Agency, in considering the known impurities, does not believe that they singly or in aggregate represent any potential hazard or are they of significance in establishing residue levels.

3. Physical and Chemical Properties

A nearly complete range of data is available on the physical and chemical properties of sulprofos. Data which are not available, but which are required, are listed within the Chapter III data charts. Those data which are available are as follows:

Appearance	Tan colored liquid (Mobay Chemical Corp., 1975, MRID GS0076-150)
Boiling point	155 - 158° C @ 0.1 mm Hg (Mobay Chemical Corp., 1975, MRID GS0076-152)
Odor	Typical phosphorous odor (Mobay Chemical Corp., 1975, MRID GS0076-150)
Melting Point	<-50° C (Mobay Chemical Corp., 1975, MRID GS0076-150)
Hydrolysis rate	@ 25° C and pH 7 - Half-life 6 months @ 25° C and pH 11 - Half-life 6 days (Mobay Chemical Corp., 1975, MRID GS0076-152)†
Specific Gravity	1.2 @ 20° C (Mobay Chemical Corp., 1975, MRID GS0076-150)
Solubility	Low solubility in water - 0.3 ppm @ 20° C High solubility in organic solvents (Mobay Chemical Corp., 1975, MRID GS0076-150)
Viscosity	22.5 cps @ 20° C (Mobay Chemical Corp., 1975, MRID GS0076-150)
Vapor Pressure	<0.05 mm Hg @ 20° C (Mobay Chemical Corp., 1975, MRID GS0076-152)
Wt. per Gallon	10 lbs (Mobay Chemical Corp., 1975, MRID GS0076-150)

4. Storage Stability

Technical sulprofos has been evaluated for its physical and chemical stability. Accelerated storage studies have been conducted for eight week periods at 50° C and twenty-four week periods at 40° C. The test results have provided sufficient information to permit an extrapolated shelf-life in excess of two years (Synek and Gonzalez, 1975, MRID GS0076-178).

B. Product Chemistry - End Use Sulprofos

Bolstar® 6, at the time of publication of this Standard, is the only sulprofos containing end use product registered with the Agency. Bolstar® 6 is an

emulsifiable concentrate formulation containing 64 percent manufacturing-use sulprofos, 15.0 percent petroleum distillate and 21 percent inert ingredients. Complete details of the formulating process and inert constituents have been made available to the agency (Mobay Chemical Corp., 1975, MRID GS0076-149; Mobay Chemical Corp., 1975, MRID GS0076-150). These items of data, like the technical synthesis process, are trade secret and will not be described within this Standard.

1. Physical and Chemical Properties

Data are available describing the following physical and chemical properties of Bolstar® 6:

Appearance	Amber (Mobay Chemical Corp., 1975, MRID GS0076-150)
Explosiveness	No explosive characteristics (Mobay Chemical Corp., 1975, MRID GS0076-152)
Flash Point	105° F (TCC) 125° F (TOC) (Mobay Chemical Corp., 1975, MRID GS0076-150)
Odor	Typical phosphorus odor (Mobay Chemical Corp., 1975, MRID GS0076-150)†
Specific Gravity	1.11 @ 20° C (Mobay Chemical Corp., 1975, MRID GS0076-150)
Solubility	Miscible with HAN solvents - not miscible with kerosenes or diesel oils (Mobay Chemical Corp., 1975, MRID GS0076-150)
Vapor pressure	<5 mm Hg @ 20° C (Mobay Chemical Corp., 1975, MRID GS0076-152)
Viscosity	45 cps @ 30° F 20 cps @ 60° F (Mobay Chemical Corp., 1975, MRID GS0076-152)
Wt. Active per Gallon	6 lbs. (Mobay Chemical Corp., 1975, MRID GS0076-150)
Wt. per Gallon	9.27 lbs. (Mobay Chemical Corp., 1975, MRID GS0076-152)

2. Storage Stability

Like technical sulprofos, Bolstar® 6 has been evaluated as to its storage stability. No change in emulsification characteristics, physical or chemical properties were observed following eight weeks at 50° C and 24 weeks at 40° C (McGreavy et al., 1975, MRID GS0076-142 and Synek and Gonzalez, 1975, MRID GS0076-178). It was noted that some decoating and corrosion occured when the test material was placed in double clear phenolic-coated steel pails. No corrosion was observed in pails having pigmented vinyl phenolic coatings.

V. ENVIRONMENTAL FATE

A. Use Profile
B. Environmental Fate Profile

A. Use Profile

Sulprofos is a broad spectrum organophosphate insecticide/acaracide conditionally registered on February 14, 1979, for control of tobacco budworm, cotton bollworm, lygus nymphs, fall armyworm, beet armyworm, pink bollworm and fleahoppers on cotton. In addition, the labeling for Bolstar® 6, the only registered end use product, bears claims for suppression of lygus adults, whiteflies, and spider mites (Carmine and two-spotted).

Bolstar® 6 is formulated as a 64 percent sulprofos emulsifiable concentrate containing 15 percent aromatic petroleum distillate and 21 percent inert ingredients. Application may be made, at the specified dosage, by either air or ground equipment. The concentrate is to be diluted with that amount of water required to ensure complete foliar coverage. Aerial applications may not, however, be made at dilutions of less than 1 gallon per acre. Application rates for all states other than California and Arizona vary by target pest and infestation level; falling within a range of 2/3 to 2 pints of undiluted formulation per acre (equivalent to 0.5 to 1.5 lbs. active sulprofos). Use directions specific to Arizona and California prescribe a minimum application rate of 1-1/3 pint (1 lb. active ingredient) per acre and a maximum rate of 2 pints. Applications, without regard to geographical region, may be made at three to seven day intervals. Total application is restricted to 20 pints per acre/season with the last application no closer to harvest than 21 days in California and Arizona, or 14 days in all other states.

Use and usage data relating to sulprofos are limited due to its recent appearance in the marketplace. Although there are no formal survey data available regarding predominate application rates, preliminary information provided by Mississippi State University (Preliminary Benefits Analysis: EPN/Cotton 1981, MRID GS0076-184) indicates that sulprofos is commonly applied at the rate of 1.0 lbs. a.i. per acre for control of the Heliothis complex. Based upon an assumed average application of 1.0 lb. per acre, the Agency estimates that a 1980 usage of 813,800 pounds a.i. (Weiler, E., 1981, MRID GS0076-183).

B. Environmental Fate Profile

1. Hydrolysis

Sulprofos is considered to be relatively stable in acidic and neutral aqueous buffer solutions. In an aqueous buffer solution at pH 3 and at 40° C, sulprofos hydrolyzed to phenol sulfoxide (0.5 percent) and sulprofos sulfoxide (4.8 percent) in 16 days. At pH-7 and at 40° C, only 8 percent of the test sulprofos had hydrolyzed and/or oxidized within 16 days; the products being phenol sulfoxide (0.8 percent) and sulprofos sulfoxide (7.2 percent) (Bull, D.L. et al., 1975, MRID GS0076-034).

Sulprofos may be considered unstable when subjected to basic buffer solutions. In an aqueous buffer solution at pH-11 and at 40° C, sulprofos was more than 50 percent hydrolyzed in four to eight days. The hydrolysis products were phenol sulfoxide (35.8 percent), phenol sulfide (32.0 percent) and sulprofos sulfoxide (3.2 percent) (Bull, D.L. et al., 1975, MRID GS0076-034).

In a simulated pond study, sulprofos was half degraded in approximately two hours and completly degraded in four days. At the fourth day, the degradation products were: phenol sulfoxide (54.7 percent), sulprofos sulfoxide (14.4 percent), phenol sulfone (0.6 percent), and 9.4 percent unidentified. Further conversion of degradation products occurred. At day 16, the degradation products were, phenol sulfoxide, 66.9 percent, sulprofos sulfoxide, 1.4 percent, and unidentified products comprised 12.1 percent (Bull, D.L., et al. 1975, MRID GS0076-034).

From these data, the Agency may conclude that sulprofos, upon finding its way into aquatic environments through either leaching, runoff or inadvertent application, may degrade fairly rapidly. One of the principal products, however, is noted as being a cholinesterase (ChE) inhibitor. The significance of these findings, shall be addressed in relation to the potential for sulprofos to enter aquatic environments.

2. Photodegradation

(a) Aqueous

In an aqueous phosphate buffer solution (pH-7), sulprofos was 1/2-photolyzed in seven hours at 20° C. Photolysis slowed at 5° C, with 36 hours being required before reaching 1/2. The principal photo product was the P=S sulfoxide (PSSO) which accounted for approximately

22 and 18 percent of the activity at day-3 at 20° C and 5° C respectively. At day-3, approximately 1 percent of the activity was P=S sulfone ($PSSO_2$) and about 2 percent of the activity was parent phenol at both temperatures. The remaining activity, which amounted to approximately 13 percent at 20° C and 7 percent at 5° C, was unidentified (Atwell and Gronberg 1975, MRID GS0076-026).

(b) Soil

The photodecomposition half-life of sulprofos at 20° C has been extrapolated to be approximately 12 days on silty loam soil. Photodecomposition proceeds more slowly at 5° C, with the extrapolated half-life not occurring for approximately 32 days. In silty loam at 20° C, the major photo product and or metabolite (PSSO), accounted for approximately 68 percent of the activity at 28 days. At 5° C, approximately 63 percent of the activity was PSSO.

The photodegradative half-life of sulprofos on sandy loam at 20° C has been extrapolated to be 12 days. At 5° C, the half-life has been extrapolated to be 15 days. At 20° the major oxidative product, PSSO, accounted for 62 percent of the noted activity at 28 days and was slightly decreasing at this time. When observed at 5° C, PSSO, accounted for approximately 78 percent of the noted activity at 28 days.

In silty loam, at 20 and 5° C and in the absence of light, sulprofos under went oxidation to PSSO at approximately 22 percent and 18 percent respectively within 28 days. In sandy loam, oxidation to PSSO was approximately 28% for both temperatures (Atwell and Gronberg, 1975, MRID GS0076-026).

(c) Glass Surface

On glass surfaces, at 20°C, sulprofos photodecomposed with a half-life of approximately 19 hours. P=S sulfoxide, the major photolysis product was about 25 percent (maximal) of the activity at 2 days and declined to approximately 5 percent of activity at 14 days. Approximately 60 percent activity was unaccounted for at 14 days (Atwell and Gronberg, 1975, MRID GS0076-026).

At 5° C, the half-life of sulprofos was approximately 63 hours. P=S sulfoxide, the major photolysis product reached maximal, approximately 30 percent of the activity, at 5 days. The P=S sulfoxide was approximately 5 percent of the activity in 14 days, with approximately 30 percent of the activity unaccounted for after 14 days. The loss of applied activity throughout the 14 days suggests that the photolysis products may be volatilized from glass surfaces.

(d) Silica Gel Surface

Sulprofos was 1/2-photolyzed in approximately one hour on silica gel surfaces. The primary photoproduct was the P=S sulfoxide (PSSO) which reached a maxima of 77 percent of the activity in 6 hours, then proceeded to decline to 69 percent of the activity in 24 hours. The minor photoproducts were the P=S sulfone ($PSSO_2$), parent phenol (PS) and phenol sulfoxide (PSO). Sixteen percent of the activity was unidentified after 24 hours.

The rate of photodegradation was slower at 5^{o} C. The half-life was approximately 2 hours. P=S sulfoxide (PSSO) was the major photo product, accounting for 76 percent of the activity after 24 hours. Minor photo products were observed. Approximately 17 percent of the activity was unidentified.

In the absence of light, sulprofos was stable on silica gel surfaces at both 5 and 20^{o} C (Atwell and Gronberg, 1975, MRID GS0076-026).

Given the preceding data, the Agency concludes that sulprofos may be anticipated to undergo fairly rapid photodegradation with the principal photodegradate product being P=S sulfoxide.

3. Aerobic Soil Metabolism

Under aerobic soil conditions, sulprofos degrades fairly rapidly. The extrapolated half-life in loam, sandy soil or construction sand ranges from one to four weeks. The half-life appears greatest (near four weeks) in loam. Three major metabolites have been identified. These metabolites are sulprofos sulfoxide, sulprofos sulfone, and phenol sulfoxide (unique to construction sand). These major metabolites are reasonably long lived with a $\geq$ 128 day half-life. Trace amounts (1-2 percent of applied activity) of O-analog sulfoxide, O-analog sulfone, phenol sulfoxide are also present without regard to soil type. Unextractable residues account for 10-25 percnt of applied activity at approximately 170 days. Loam soils produce more sulprofos sulfoxide than sandy soils. The presence of organic matter, the oxygen content of the soil and pH are major factors in the degradation of sulprofos. Degradation appears, however, to be via physicochemical pathways with biological degradation not a major contributor (Pither, 1978, MRID GS0076-167)

From the review of available data, the Agency has concluded that sulprofos may be anticipated to degrade fairly rapidly under most aerobic soil conditions. In light of the pattern of use under consideration, aerial or ground application not to include soil incorporation, it may be anticipated that the majority of the applied sulprofos parent reaching the soil will be degraded via physicochemical pathways in the manner described above.

4. Anaerobic Soil Metabolism

Under anaerobic conditions, degradation proceeds in a manner similar to that observed under aerobic conditions with the exception that the degradative process occurs much more slowly. The extrapolated half-life for sulprofos under anaerobic soil conditions is approximately 20-30 weeks (Bull et al. 1975, MRID GS0076-034).

5. Microbial Degradation

Few groups of microbes appear to possess the ability to degrade sulprofos. Of those that have demonstrated the ability to affect degradation, it appears that they may do so only in small amounts. Bacteria and Streptomyces have a potential to degrade sulprofos, while fungi have demonstrated no degradative activity (although incorporation into the mycelia is reported) (McNamara, F.T., 1978, MRID GS0076-143).

6. Metabolism - Effect of Sulprofos on Microbes

Representative species of bacteria, fungi, and streptomyces (Bacillis , Cellulomonas , Pseudomonas , Streptomyces , Aspergillus , Penicillium , Tricoderma , and Phycomyces spp. have been evaluated against $2\text{-}10^4$ ppm concentrations of sulprofos (LaBlanc, B., et al., 1975, MRID GS0076-108). No inhibition of any organism has been demonstrated at concentrations of less than 10 ppm. Fungi, when exposed at 10 ppm exhibit slight inhibition, with marked inhibition occuring at 100 ppm. Bacteria, Streptomyces and Tricoderma were not inhibited at the highest concentration tested.

Nitrification and denitrification potentials in loamy sand soil do not show any effect at either 1X or 10X labeled rates of application (Strankowski, K.J., 1978, MRID GS0076-177).

Nitrogen fixation, as measured by studies involving the symbiotic relationship between Rhyobium and soybeans, appears markedly reduced at four weeks (67%). This reduction indicates a potential break in the nitrogen cycle and/or increased persistence. The limits of the test method appear to preclude distinguishing whether the observed effect is related to an effect upon the plant or the microbe (Strankowski, K.J., 1978, MRID GS0076-177).

The Agency may conclude from reviewed studies that application of sulprofos at rates of 0.5 to 1.5 lb. a.i./A would not be anticipated to affect discernable alterations in soil microbe populations. Given, however, an indication of a significant reduction in nitrogen fixation, some measure of concern must remain. In this latter regard, the Agency believes that observed effects may have resulted from an effect not directly related to Rhyobium inhibition. The Agency would, therefore, propose a reinvestigation with provision made for an observation of effects to both symbiots. A reevaluation

of sulprofos's impact upon nitrogen fixation shall not be imposed as a condition of its registration for cotton application. Should, however, future registration(s) be sought for crops for which nitrogen fixation is an important factor (primarily legumes), the Agency may require a reinvestigation.

7. Plant Metabolism (Dislodgable Residues)

Approximately 50% of ^{14}C or ^{32}P labeled sulprofos, when applied to cotton leaves is absorbed within 24 hours. While residues can be recovered from treated leaves throughout either 16 or 32 day studies, all compounds are essentially depleted in 8 days. Compounds recovered from leaf surfaces and their percent of applied dose at 8 days are as follows: (1) sulprofos parent (0.0%), (2) sulprofos sulfoxide (0.2 percent), (3) sulprofos sulfone (0.2 percent) (4) O-Analogue sulfone (0.0 percent), (5) Phenol sulfoxide (0.0 percent) Phenol sulfone (0.1 percent), (7) unknown (0.7 percent). Studies have provided that at day one these residues were 2.2, 13.7, 4.1, 0.2, 0.8, 0.7, and 3.9 percent respectively. Internal extracts of treated leaves have been found to include the same radioactive compounds as in the external rinses plus water solubles, unextractables, and lost activity (Bull and Whitten, 1975, MRID GS0076-034).

8. Leaching

Sulprofos, when evaluated with respect to its leaching ability, (Atwell and Gronberg, 1975, MRID GS0076-025), (Atwell and Gronberg, 1975 MRID GS0076-024) was found to be largely retained within the upper two inches (about 95%) in muck, loam and silty loam soil. It was found mobile in sandy loam. As organic matter content of soil decreases and pH increases, leaching of sulprofos may be expected to increase. In thin layer mobility studies, sulprofos was found to leach very little in agricultural sand, sandy loam, sandy clay loam, silt loam and two silty clay soils. In an aged soil study, approximately 90 percent of aged soil degradates were distributed in the upper four inches of a loam soil column, with about 8.8 percent occurring in the leachate as sulprofos phenol sulfone. This indicates that in basic soils, leaching of the phenol sulfone may be significant in sandy loam or soil with low organic matter.

From the evaluated data, the Agency may conclude that sulprofos parent and certain of its degradates may leach in sandy soils. There is additionally evidence that some movement of degradation products can occur in other soil types. The reasonably insoluble nature of the parent compound (0.03 ppm) (Mobay Chemical Corp., 1975, MRID GS0076-150), and an Agency calculated soil/water partition coefficient of 69 leads the Agency not to believe that movement of sulprofos per se is of immediate concern. Due to the single pattern of use under consideration within this standard being application to cotton, the Agency, further, does not believe that the indicated potential for leaching in sandy soil is of significance, because cotton is not customarily

cultivated in sandy soil types. A full understanding of the potential for movement from treated areas into aquatic systems, however, can not be developed until such time as the Agency may obtain and evaluate adsorption/desorption data for both parent sulprofos and its principal degradation products. A reconsideration of the significance of sulprofos's leaching potential will be conducted upon receipt of these data. The Agency will additionally reconsider the significance of sulprofos's leaching potential should sandy soil cultivated crops such as citrus, peanuts, etc. be proposed for future labeling consideration.

9. Runoff

Data available for Agency review have indicated that residue in runoff water was, under the conditions of the test, generally less than 10 percent (0.3 ppm) of the applied active on sandy loam, loam and clay loam for 8 and 12 ft. lanes. Approximately 25 percent (0.75 ppm) runoff occurred for loam soil in 6 ft. lanes (Kurtz and Gronberg, 1975, MRID GS0076-106).

The principal oxidative product found in the runoff water was sulprofos sulfoxide (amounting to 67-70 percent of the residue). Sulprofos sulfone and sulprofos oxygen analog sulfoxide residues ranged from 8-23 percent. Small amounts (2 percent or less) of sulprofos parent and sulprofos oxygen analog sulfone were detected in runoff water.

As with leaching, the Agency considers soil runoff to be one of the principal mechanisms by which pesticides may move from treated crop areas into aquatic environments. Those data reviewed by the Agency have indicated that sulprofos and its degradates possess a limited potential for movement by means of runoff. The Agency, however, again believes that a full understanding of sulprofos's runoff potential cannot be obtained until such time as the Agency may review adsorption/desorption data. With these data, the Agency will be in a position to provide a calculated estimated environmental concentration (EEC).

10. Field Dissipation

In test data reviewed by the Agency, combined residues of 2.45 ppm and 1.92 ppm persisted for 242 days in clay loam and loam respectively from 3 sucessive applications (2.5 ppm) at 30-day intervals. Combined residues in sand were approximately 2.5 times the application rate at 72 days. In muck, combined residues were more than 14 times the theoretical value (2.5 ppm) at 72 days. The data show, however, that the photodegradative half-life of sulprofos on soil surfaces of four different soil types was 12 to 32 days (Chemonics Industries, 1978, MRID GS0076-056, -057, -058, -059). From these data, the Agency may deduce that soil incorporation of sulprofos would provide for greater field persistence. As some portion of the applied sulprofos would be intercepted by the cotton plants and crop uptake studies under actual use

conditions show that combined soil residues at harvest range from 0.03 to 0.35 ppm for 15 to 18 applications at 2.5 to 3.25 lb/A, the Agency believes that soil residues resulting from sulprofos application to cotton would be within acceptable limits.

Although the Agency has determined that those data derived from muck soil testing are inadequate, the Agency will not, for the current use pattern, require additional data. Should future registration actions involve crops customarily grown in muck soil, the Agency will require acceptable muck soil persistence data as a condition of registration.

11. Bioaccumulation

The bioaccumulation potential of sulprofos has been investigated in a study involving channel catfish (Lamb and Roney, 1975, MRID GS0076-139). The fish, exposed at 10 ppb through a 28 day period, were sacrificed and analyzed for residue content and physical location of residues within the body. Accumulation factors for whole fish were from 704 to 1006 (2816 to 4025 ppb). Approximately 88 percent of extractable ^{14}C residues were contained in the nonedible portion and 12 percent in the edible portion on day 28 of exposure (3287 ppb in non-edible and 448 ppb in edible). Of the ^{14}C residue in non-edible polar extract, 21 percent was identified as sulprofos parent. The remaining residue was identifed as Sulfoxide (PSS) (44 percent), Sulfone ($PSSO_2$) (2 percent), and Oxygen Analog Sulfoxide (POSO) (1.0 percent). An additional 17 percent of the identifiable activity was accounted for as Sulfoxide and Sulfone phenols. Approximately 17 percent of the total activity was unidentified.

During withdrawal, approximately half of the accumulated ^{14}C residue in the catfish was eliminated within 5 hours. This rapid elimination tends to indicate that most of the residues were on the scales or in viscera and not in edible tissue. Following 28 days of withdrawal, 112 ppb of residue was detected in whole body analysis.

The preceding study, although not conducted in strict accord with the Agency Guidelines protocol, has been deemed acceptable. Given the rapid degradation of sulprofos (refer to the above noted simulated pond study), the rate of elimination of residues from catfish when placed in pesticide free water, and the dilution of residue in water, the Agency does not expect that residues of sulprofos would persist for a sufficient period of time to result in accumulation in fish.

12. Accumulation: Rotational Crop Uptake

Although no petitions for tolerance for rotational crops are pending with the Agency, some data are available. These data provide that for sugar beets 164 days after last application (285 days planting to harvest) residues were

0.016 ppm in the roots, 0.008 ppm in the tops and 0.36ppm in (0-6") soil layer. A second study conducted on sugar beets provided results indicating the presence of residues 365 days following the last application (174 days planting to harvest). These residues were identified at levels of 0.009 ppm in the roots, 0.005 ppm in the tops and 0.29 ppm in the soil (Sandi, F.E., 1978, MRID GS0076-173).

Studies conducted on rotational wheat similarly reveal the presence of residues. Wheat planted 164 days following last application (170 days planting to harvest) yielded residue levels of 0.017 ppm in the grain, 0.044 ppm in the chaff, 0.047 ppm in the stalk and 0.121 ppm sulprofos ^{14}C-equivalent in the forage. Wheat planted 365 days following the last application (174 days planting to harvest) contained residue levels of 0.036 ppm in the forage. At 125 and 66 days planting to harvest residues were 0.088 and 0.126 respectively (Sandi, F.E. 1978, MRID GS0076-173).

Residues in potato tubers planted 131, 203, 197, and 173 days after last application (as ppm sulprofos equivalents) in Georgia, Texas (1), Mississippi, Florida, were all <0.01 ppm. Texas (2) had a residue value of 0.01 ppm at 203 days. Soil residues (0-6" depth) at planting and harvest were 0.72, 0.15; 0.36, 0.14; 0.03, 0.35; 0.28, 0.15; 0.01, 0.03 ppm respectively (Analytical Bio Chemistry Laboratories, 1978, MRID GS0076-008, -009, -010, -011).

Residues in cucumbers (fruit) planted at 88 days post application in Texas (both studies) were <0.01 ppm (Analytical Bio Chemistry Laboratories 1978, MRID GS0076-001).

Residues in soybeans (as threshed beans) planted 239, 261, and 287 days following last application in Mississippi, Georgia, and Texas (two studies) were <0.01, <0.01, 0.02, and 0.25 ppm respectively. Soil residues (0-6" depth) at planting and harvest were 0.11, 0.14; 0.04, 0.32; 0.02, 0.02; 0.26, 0.28 ppm respectively (Analytical Bio Chemistry Laboratories, 1978, MRID GS0076-008, -013, -014, -015).

Residues in soybeans (as dry vines) planted 239, 261, 287, and 300 days after last application in Mississippi, Georgia, Texas (two studies) and Florida were 0.03, 0.17, 0.15, 2.05, and <0.01 ppm respectively. Soil samples (0-6") were 0.11, 0.14; 0.04, 0.32; 0.02, 0.02; 0.26, 0.28; not available, and 0.07 ppm respectively (Analytical Bio Chemistry Laboratories, 1978, MRID GS0076-008, -012, -013, -014, -015).

On the basis of the available data, the Agency believes that a six month crop rotational restriction is sufficient for potato tubers and cucumbers for all areas tested. Similarly, the Agency believes that a 60 day rotational crop restriction would be sufficient for turnips and peas. Significant residue levels do, however, occur in soybeans at 12 months. As insufficient data are available, and no petition for a rotational crop tolerance has been proposed, the Agency will impose a rotational crop restriction upon all crops other than potatoes, cuicumbers, turnips and peas. These latter crops, at the option of the registrant, may be identified upon labeling as being crops which may be rotated following a six month interval.

VI. TOXICOLOGY

A. Toxicology Profile - Manufacturing-Use Sulprofos
B. Toxicology Profile - End Use Product(s)
C. Human and Domestic Animal Hazard Assessment

Toxicology - Manufacturing-Use Sulprofos

Toxicology Profile

Data meeting nearly all Agency requirements with regard to a toxicological characterization of manufacturing-use sulprofos have been submitted and evaluated. For the purpose of this Standard, manufacturing-use and the technical chemical shall be viewed as synonymous terminology. The results and conclusions pertinent to these investigations are noted below in order of their appearance as Guideline requirements.

2. Acute Oral

The acute oral toxicities of sulprofos technical, sulprofos analytical standard, the sulfone, sulfoxide, and the oxygen analogues of sulprofos and sulprofos sulfoxide have been adequately delineated through laboratory evaluations utilizing male and female test rats. These oral toxicities have been defined as follows:

a. Technical Sulprofos (Lamb and Matzkanin, 1975, MRID GS0076-125)
(Lamb and Matzkanin, 1975, MRID GS0076-126)
(Lamb and Matzkanin, 1978, MRID GS0076-130)
(Lamb and Matzkanin, 1978, MRID GS0076-131)

LD_{50} male 262 (211-326) mg/kg
LD_{50} female 275 (201-376) mg/kg

b. Sulfone (Lamb and Matzkanin, 1978, MRID GS0076-132)

LD_{50} male 283 (222-361) mg/kg
LD_{50} female 404 (329-496 mg/kg

c. Oxygen analogue of sulfone (Lamb and Matzkanin, 1978, MRID GS0076-133)

LD_{50} male 74 (47-115) mg/kg
LD_{50} female 133 (114-155) mg/kg

d. Sulfoxide (Lamb and Matzkanin, 1978, MRID GS0076-134)

LD_{50} male 263 mg/kg
LD_{50} female 283 (243-330) mg/kg

e. Sulprofos analytical standard (Lamb and Matzkanin, 1978, MRID GS0076-135)

LD_{50} male 208 (172-251) mg/kg
LD_{50} female 356 (306-416) mg/kg

f. Oxygen analogue of Sulprofos (Lamb and Matzkanin, 1978, MRID GS0076-136)

LD_{50} male 73 (53-98) mg/kg
LD_{50} female 206 (142-299) mg/kg

g. Oxygen analogue of sulfoxide (Lamb and Matzkanin, 1978, MRID GS0076-137)

LD_{50} male 62 (47-80) mg/kg
LD_{50} female 84 (67-104) mg/kg

From these data, the Agency may conclude that sulprofos technical and its metabolites may, when ingested, present a moderate acute hazard to humans. The range of LD_{50} values fall within those parameters provided under Toxicity Category II.

3. Acute Dermal Toxicity

Data fulfilling all Agency requirments with regard to testing in relation to the acute dermal toxicity of manufacturing-use (technical) sulprofos have been submitted and reviewed (Lamb and Matzkanin, 1975, MRID GS076-122). The results of these studies are as follows:

a) Rat dermal LD_{50} - male - >1,000 mg/kg
female - >1,000 mg/kg

b) Rabbit Dermal LD_{50} - male - 820 (599-1123) mg/kg
female - 994 (492-2009) mg/kg

The preceding acute dermal toxicity data are adequate to permit an evaluation of the dermal hazard presented by sulprofos technical to mammalian species. These data indicate that manufacturing-use sulprofos may be considered moderately toxic through dermal absorption. The range of LD_{50} values fall within those parameters provided under Toxicity Category II.

Acute Inhalation Toxicity

Data fulfilling Agency testing requirements with regard to the acute inhalation toxicity of manufacturing-use sulprofos have been obtained and reviewed by the Agency. These test data were developed through the exposure of rats, mice, and hamsters at multiple exposure levels and durations. The aggregate test data indicate that, for all species tested, the acute inhalation LC_{50} values are all greater than 0.5 mg/L (Kimmerle, G. 1975, MRID GS0076-102). The Agency may, therefore, conclude that manufacturing-use sulprofos may be considered moderately toxic by means of inhalation. The LC_{50} values place sulprofos within Toxicity Category II.

Primary Eye Irritation

Data fulfilling Agency requirements regarding the primary eye irritation potential of manufacturing-use sulprofos have been received and reviewed by the Agency. These data provide that upon placement of 100 microliters of sulprofos technical within the conjunctival sack of rabbits for exposure periods of 5 minutes and 25 hours, no irritation was observable through the seven day observation period (Groning and Kimmerly 1975, MRID GS0076-092). The Agency may, therefore, conclude that manufacturing-use sulprofos can be considered non-irritating to the eyes. The failure of sulprofos to produce observable eye irritation places it within Toxicity Category IV for this criteria.

5. Primary Dermal Irritation

All data requirements with respect to the characterization of manufacturing-use sulprofos's potential for causing dermal irritation have been fulfilled. The Agency, upon review of these data has determined that sulprofos induces no erythema or edema when applied to either intact or abraded skin (Gronig and Kimmerle 1975, MRID GS0076-092). The failure of sulprofos to produce observable skin irritation at 72 hours post administration places it within Toxicity Category IV for this criteria.

6. Dermal Sensitization

The Agency has received and reviewed a dermal sensitization study conducted with manufacturing-use sulprofos. From these data, the Agency has determined that the irritation produced by the challenge injections was not substantially higher for any reaction evaluation parameter (erythema, edema, diameter) than for the sensitizing injections (Lamb and Anderson 1976, MRID GS0076-118). The Agency has, therefore, concluded that manufacturing-use sulprofos is not a sensitizing agent by dermal application.

7. Acute Delayed Neurotoxicity

Data relative to the delayed neurotoxic potential of manufacturing-use sulprofos have been made available by the registrant. These data provide the results of studies involving the dosing of hens at rates ranging from 25 to 250 mg/kg. Surviving birds were observed for 28 days prior to sacrifice. Although normal signs of organophosphate poisoning persisted for up to eleven days, clinical as well as histological examination produced no indication of delayed neurotoxicity (Thyssen and Siegmund 1975, MRID GS0076-181). On the basis of these data, the Agency has concluded that manufacturing-use sulprofos possesses no inherent potential for delayed neurotoxicity.

8. Subchronic Oral Toxicity

Agency review of submitted subchronic oral toxicity data have provided that, in the rat, dose levels of 30, 100, and 300 ppm resulted in depression of plasma cholinesterase. Erythrocyte cholinesterase depression occurred at levels of 100 ppm and above as did brain cholinesterase; the latter occurring only in the female at the 100 ppm level. There were no observable effects related to hematology, blood chemistry, urine analysis and macroscopic or microscopic pathology. The no observed effect level (NOEL) established as a result of these data was 10 ppm (Groning and Dieckman, 1975, GS0076-091).

A second subchronic oral toxicity study involving 90-day administration of sulprofos to dogs has been reviewed by the Agency. Although this study has been ruled supplemental due to the failure of the study to provide for a full six month test duration, no additonal data shall be required due to the adequacy of the chronic studies which shall be noted later in this chapter. The results of this study, are, however, of interest to the Agency. The data provide that both male and female animals, dosed at the 200 ppm level, showed a significant decrease in body weight change; males also demonstrated significantly lower feed consumption. At 200 ppm, both sexes showed signs of intoxication, diarrhea and regurgitation with some rear leg involvement occuring in the females. There were additionally shifts in blood chemistry, histologic lesions and cholinesterase depression at the 200 ppm level. At the 20 ppm level, plasma cholinesterase depression was the only dose related effect. No observable effects were apparent at the 10 ppm level (Lamb, 1975, MRID GS0076-110).

9. Subchronic Inhalation

Limited data are available to the Agency concerning the subchronic inhalation toxicity of manufacturing-use sulprofos. The single available study must be judged supplemental due to the duration of the test, 21 days, falling short of the prescribed 90-day exposure period. The Agency does not, however, consider the lace of these data to be critical. Due to both the pattern of chemical

use, and the outcome of the available chronic studies, the Agency believes the potential effects resulting from anticipated subchronic inhalation exposure to warrant little concern. Although only supplemental, the results from available testing indicate that up to concentration levels of 14 mg/m^2, no physical appearance, growth rate, or behavioral changes occur. It may be additonally noted that an evaluation of the clinical chemistry, hematology, urinalyses, macroscopic pathology and histopathology indicated no variation from normal (Kimmerle 1975, MRID GS0076-103).

10. Oncogenicity

The Agency has received and reviewed a two-year feeding study on Fisher 344 rats. Dietary dosages of 0, 6, 60 and 250 ppm sulprofos were administered in accordance with accepted test protocol. Body weights, organ weights and food consumption were not affected at any level, except for high dose female groups which consumed relatively more food, but maintained weight. Blood chemistry, hematology and urinalysis were normal for all groups with the exception of cholinesterase (ChE). Plasma and red blood cell (RBC) ChE were depressed at 60 and 250 ppm for males and females, with Brain ChE inhibited only at 250 ppm for both sexes. At 6 ppm no significant inhibition was noted. Gross histopathology showed no compound related effects, or tumor formation. The ChE no effect level (NOEL) for the rat has been established at 6 ppm (Lamb, 1978, MRID GS0076-114).

In a similar study, Swiss mice were fed at levels of 2.5, 25, 200 and 400 ppm for 22 months. The only significant findings of this study were related to ChE inhibition. Plasma and RBC ChE were significantly inhibited at 25 ppm and above, with brain ChE inhibition becoming apparent at 400 ppm. All other parameters evaluated by the study showed no compound related effect. Gross and histopathology showed no somatic or oncogenic effect. The ChE NOEL,established for the mouse is 2.5 ppm (Lamb, 1978, GS0076-115).

An additional two year feeding study involving the dosing of beagle dogs at levels of 10, 100 and 150 ppm has been evaluated by the Agency. In this study, the only affected parameter was ChE. At 100 and 150 ppm plasma, RBC and brain ChE were inhibited. The established ChE NOEL for the dog is 10 ppm with no somatic effects at 150 ppm (Lamb, 1978, MRID GS0076-117)

Given the results of the available data, the Agency has concluded that sulprofos poses no significant oncogenic risk. In addition, conversion of the ChE NOEL into mg/kg/day for each of the three species noted above, provides an adequate basis for acceptable daily intake calculation (ADI). The lowest value, that calculated for the dog (0.25 mg/kg/day), shall be used by the Agency for all ADI calculations.

11. Teratogenicity

Sulprofos has been evaluated for teratogenic potential in a single study involving the dosing of rabbits from the time of implantation through the period of major organogenesis (days 6 through 18). The rabbits were orally dosed at rates of 3, 10 and 30 mg/kg/day. Fetuses derived by ceasarean section showed neither skeletal nor visceral abnormalities (Machemer 1975, MRID GS0076-141).

While the Agency believes that the preceding teratogenicity study, coupled with the three generation reproduction study to be detailed below, are a reasonable indication of sulprofos' nonteratatogenicity, the Agency shall require a confirmatory test as proposed under Guideline section 163.83-3. For additional information with regard to the rational underpinning this requirement, refer to Chapter III.

12. Reproduction

The potential reproductive effects of sulprofos have been evaluated in a three generation study. Male and female rats were subjected to exposure levels of 30, 60, and 120 ppm under conditions of established protocol. Following evaluation of two litters per generation through three generations, it was found that reproductive performance and reproductive indexes were not affected at any level (Hazelton Laboratories America, Inc. 1978, MRID GS0076-095). The reproductive effect NOEL established as a result of these data is 120 ppm. On the basis of these data, the Agency believes that sulprofos posesses no potential for mammalian reproductive impairment.

13. Mutagenicity

The mutagenic potential of sulprofos has been assessed in a single dominant lethal assay. Male mice were dosed at 200 mg/kg, and mated weekly for eight weeks to virgin females. Implantation losses and fetal survival were not affected throughout the observation period (Machemer, 1975, MRID GS0076-140)

Although the available dominant lethal assay does serve as partial evidence that sulprofos is nonmutagenic, it can not be ruled as conclusive. The Agency requires four studies relating to potential heritable effects. These studies involve a mamalian in-vitro point mutation test, a sensitive sub-mammalian point mutation test, a primary DNA damage test and a mammalian in-vitro cytogenetics test. The available dominant lethal assay will be considered as acceptable in fulfilling the requirment for a mammalian in-vitro cytogenetics test. For additional information related to additional mutagenicity test requirments, see Chapter III.

14. General Metabolism

Consistent with the findings of those studies discussed within the Environmental Fate chapter of this standard, a general metabolism study conducted with female white rats has demonstrated that sulprofos metabolizes rapidly and is excreted principally in the urine (approximately 92 percent in 24 hr.). The metabolites present in the urine were water-soluble compounds which underwent conversion to free phenolic derivatives through hydrolysis with glucoronidase-aryl sulfatase or acid. Tissue analysis provided that the remaining sulprofos existed as parent compond, five phosphorus containing oxidative metabolites and three substituted phenols (Bull and Ivie, 1975, MRID GS0076-032).

B. Toxicology Profile - End Use Sulprofos

Toxicology Profile

The data provided below relate singularly to Bolstar® 6, the only registered product containing sulprofos as its sole active ingredient. Given the appearance of inert related acute effects, principally in relation to eye irritation, the Agency does not believe it sound to attempt to expand the inferences provided by these data beyond the present 64% formulation. The available data are, however, adequate to characterize the acute toxicity of Bolstar® 6.

Data have been reviewed which provide that Bolstar® 6, like manufacturing-use sulprofos, is a Category II oral toxicant with rat acute oral LD_{50}s in the range of 90 to 150 mg/kg (Lamb and Matzkanin, 1975, MRID GS0076-127). Similarly, Bolstar® 6 falls within toxicity category II in relation to its acute dermal effects (Lamb and Matzkanin, 1975, MRID GS0076-123). The established rabbit acute dermal LD_{50} values fall within the range of 750 to 850 mg/kg. The acute inhalation toxicity of Bolstar® 6 is somewhat reduced from that of the technical with the calculated LC_{50} values all being greater than 2.0 mg/L for the rat (Lamb and Matzkanin, 1975, MRID GS0076-124). Bolstar® 6, therefore, falls within toxicity category III with regard to inhalation. While Bolstar® has been demonstrated not to pose any risk with regard to either skin irritation (Lamb and Matzkanin, 1975, MRID GS0076-128), it has been shown to be irritating to the eyes (Lamb and Matzkanin, 1975, MRID GS0076-129). Product labeling, therefore, shall bear those statements consistent with a category II eye irritant.

In addition to those acute data customarily required for end-use products, the registrant has submitted an unsolicited subacute dermal study conducted on rabbits (Lamb and Matzkanin, 1975, MRID GS0076-121). Male and female animals were exposed to 100 mg applications of Bolstar® 6 for daily eight hour periods, five days a week through three weeks. All applications were made to the shaved backs of the animals. There were no observable changes in blood chemistry,

hematology, urinalysis, organ weights and gross or microscopic pathologies. As would be anticipated, erythrocyte, plasma and brain cholinesterase were significantly depressed. Only slight erythema and edema were noted following the second week. Although a less severe test than that afforded by a subacute trial involving the technical product, the absence of chronic effects, coupled with that information provided by other chronic studies, permits the Agency to waive the requirement for a 21-day subacute dermal toxicity test conducted with the manufacturing-use product.

C. Human and Domestic Animal Hazard Assessment

The sulprofos exposure profile (refer to Chapter V) provides that maximum exposure will occur to those involved in direct mixing, loading, and application. The principal routes of exposure may be anticipated to be dermal and inhalation; the latter coming from applicator exposure to spray mist. As noted above, the acute toxicity of Bolstar® 6 falls within Categories II and III depending upon route of exposure. These toxicity ranges are consistent with the majority of those organophosphate compounds commonly applied to field crops. The Agency believes that the acute hazards, as mitigated by those precautionary measures prescribed by product labeling, would be within acceptable limits. Although the Agency does not possess the full complement of chronic toxicity data, those data available for Agency review do not indicate any potential for oncogenic, teratogenic, neurotoxic or reproductive effects. The Agency, therefore, believes that Bolstar®, when used in accord with label directions, presents no chronic hazard.

The full range of sulprofos toxicity data has been reviewed against the requirements of the draft Subpart K Registration Guidelines (Exposure Data Requirements: Reentry Protection). Sulprofos neither meets nor exceeds any of the requirement criteria established under section 163.130-3(a)(1). The Agency will not, therefore, require data in support of reentry intervals.

VII. Residue Chemistry

A. Residue Chemistry Profile
B. Analytical Methods

Residue Chemistry Profile

Both the residues of parent sulprofos as well as its major metabolites are of concern. Enzyme inhibition studies have been conducted which demonstrate that the sulfoxide and sulfone derivatives of sulprofos, as well as its oxygen analog and its sulfoxide and sulfone derivatives are cholinesterase inhibiting compounds. These studies additionally indicate that inhibition activity increases with the degree of oxidation (Groning 1975, MRID GS0076-080).

The fate of sulprofos, when applied to cotton, has been characterized through radiotracer studies using uniformly ring labeled ^{14}C sulprofos or ^{32}P labeled sulprofos. It has been demonstrated that approximately 73 percent of the applied sulprofos may be found upon the surface of the treated leaves. Less than 1.0 percent of the applied activity is detectable on all other plant parts, thus demonstrating that there is essentially no translocation of sulprofos residues (Bull et al., 1975, MRID GS0076-034).

Radiolabeled field studies have demonstrated that residues are principally lost through volatilization. These studies additionally demonstrate that sulprofos undergoes oxidation and/or hydrolysis to the various phenolic metabolites which are subsequently conjugated to natural plant constituents. In field studies, approximately 15-20 percent of the activity recovered at 32 days was cholinesterase inhibiting compounds. No parent compound was detectable following eight days. At 32 days the sulfoxide was the principal component of the toxic residues (66percent%), with the sulfone and the oxygen analogue of the sulfone comprising the remaining 29 and 5 percent respectively (Bull et al., 1975, MRID GS0076-034).

Field residue studies reflecting 5-15 applications of 1 and 1.5 times the maximum labeled rate have been undertaken with cotton plants at various stages of plant development. The highest value reported was 0.36 ppm which resulted after 13 applications at the high rate and a 30 day preharvest interval. The data indicate little, if any, correlation between residue levels and preharvest intervals. Data reflecting both aerial applications and treatment of furrow irrigated cotton similarly indicate that residues would not be expected to exceed 0.5 ppm (Blocker, M., 1975, MRID GS0076-027, -028), (Huddleston, E.E., 1975, MRID GS0076-096), (Mobay Chemical Corporation, 1975, MRID GS0076-147, -148), (Nash, R.F. 1975, MRID GS0076-162), (Rowehl, E., 1975, MRID GS0076-170, -171), (Scott, A., 1975, MRID GS0076-176).

Storage stability studies determining the stability of sulprofos residues in or on cottonseed, gin trash (Atwell, S.H., 1978, MRID GS0076-021), bovine tissues and milk (Atwell, S.H., 1975, MRID GS0076-020) during frozen storage have been submitted to and evaluated by the Agency. In these studies, cottonseed, gin trash, bovine liver, muscle and fat tissues, and milk were fortified with labeled sulprofos and stored at -10°C for five months. With the exception of the liver sample, 74-96 percent of the activity was recovered as sulprfos per se and essentially all the remaining activity in these samples was present as the sulfoxide metabolite. Only 3 percent of the activity detected in the liver was parent compound. The sulfoxide and sulfone metabolites accounted for 8 percent and 13 percent respectively. Although the studies show that oxidation of the parent compound does occur in the liver, they also show that essentially all of the fortified activity would be detected as sulprofos by the enforcement method.

A cottonseed processing fraction study has also been submitted to and reviewed by the Agency. In this study, cottonseeds were treated at 1.5 times the maximum rate and were harvested one day following treatment for processing into hulls, meal, crude and refined oils and soapstock fractions. The raw cottonseed bore residue of 1.7 ppm and the hulls, meal, crude oil, refined oil and soapstock contained levels of 3.28, 0.22, 3.22, 2.29 and 1.25 respectively. The data indicate that residues do concentrate in the hulls (approximately 1.9X) and refined oil (approximately 1.3X). The Agency has, therefore, determined that the 1.0 ppm food additive tolerance for residues in cottonseed hulls and oil is appropriate. No food additive tolerances are needed for the remaining fractions (cottonseed meal and soapstock) which the Agency would expect to contain levels of approximately 0.07 and 0.35 ppm respectively (Chemagro Agricultural Division, 1975, MRID GS0076-036).

In addition to those investigations involving cotton, radiotracer studies using uniformly ring labeled ^{14}C sulprofos have been conducted to determine the fate of the parent compound and its metabolites in rats, cattle, swine and chickens. In tests involving lactating dairy cattle, it has been demonstrated that sulprofos is rapidly oxidized and/or conjugated and excreted via the urine or feces almost quantitatively. The low levels of activity found in the tissues and milk were principally (about 80%) present as phenolic metabolites Ivie, et al., 1975, MRID GS0076-099). In association with the ^{14}C labeled studies, the Agency has reviewed a cold study in which cows were fed a total of 5, 25 and 250 ppm sulprofos, the sulfoxide metabolite and the sulfone metabolite in a ratio of 1:2.5:1.5 respectively (the 5 ppm feeding level representing approximately a 40X and a 15X exaggeration factor for dairy and beef cattle diets respectively). By methods sensitive to 0.01 ppm,

residue levels in the liver samples were reported as <0.01, 0.01, and 0.03 for three cows fed at the 5 ppm level. With the exception of one fat sample with a level of 0.01 ppm, all other tissue sample residues were reported as <0.001 to 0.003 (Chemagro Agricultural Division 1975, MRID GS0076-038). Trace residues of sulprofos or its cholinesterase inhibiting metabolites may be found in bovine tissues. The Agency believes, however, that these data indicate that there is no significant tendency for residues to store in the tissue.

Metabolism of sulprofos by swine has been found to be similar to that of the cow. Essentially all activity is eliminated within 24 hours. Again, elimination is principally via the urine (93 percent and 3 percent via the urine and feces respectively). At two and four hours post treatment, only phenolic metabolites are detectable (Pither and Gronberg, 1976, MRID GS0076 -168).

In a study in which labeled sulprofos was administered orally to laying hens at 1 mg/kg (approximately equal to 18 ppm in the diet), excretion was essentially complete after 24 hours with an average total of 92.3 percent excreted. Except for 24 hour kidney samples, only the 6 hour tissue samples contained detectable residues, and of these only the liver contained sufficient activity (0.1 ppm) for analysis. No detectable activity was found in any of the egg samples collected (Flint, D.R. 1975, MRID GS0076-083). In a series of poultry studies, sulprofos residue levels were determined for meat organs and eggs (Chemagro Agricultural Divsion 1978, MRID GS0076-040, -041, -042, -043) (Mobay Chemical Corporation 1978, MRID GS0076-155). Laying hens were fed a ration containing sulprofos, sulprofos sulfoxide and sulprofos sulfone at 5, 15, 50 and 150 ppm of their diet for 28 days (the 50 ppm level reflecting an exaggeration factor of approximately 2,000). No cholinesterase inhibiting residues were detected in any of the poultry tissues or eggs of birds treated at the 50 ppm level or less by a method sensitive to 0.05 ppm. At the 150 ppm dose level, the only detectable residues were 0.22 ppm in fat and 0.05 ppm in skin.

Based upon its assessment of all those data relating to residues of sulprofos and its metabolites, the Agency finds that those tolerances previously established (43 FR 32132 July 25, 1978) are adequate. These tolerances, however, may be subject to reassessment with the receipt by the Agency of additional pertinent information.

B. Analytical Methods

The Agency requires the submission of, or reference to, validated analytical methods suitable for obtaining data on the nature and amount of pesticide residues resulting from proposed uses. One method must be suitable for tolerance enforcement. The regulatory method for determination of a pesticide in raw agricultural commodities must be capable of measuring the total toxic residue derived from the pesticide.

The analytical method developed for the acquisition of sulprofos related residue data for cotton seed and cottonseed fractions has been reviewed and has undergone a successful Agency method tryout. The procedure involves an initial extraction of the cottonseed (or hulls or meal) with acetone and chloroform in the presence of Super-Cel®. Following the stripping off of the solvents, the residues are partitioned between hexane and acetonitrile. The concentrated acetonitrile layer is chromatographed on a Florisil column. The eluate is then partitioned against benzene, oxidized with meta'-chloroperbenzoic acid to form the oxygen analog of the sulfone metabolite of sulprofos which is measured using a gas-liquid chromatograph (GLC) equiped with a thermionic detector (Sandi, F.E.,1975, MRID GFS0076-172) (Sandi and Gronberg, 1975, MRID GS0076-175). The procedure for the analysis of cottonseed oil is essentially identical with the exception that the initial step is the partitioning between hexane and acetonitrile.

Modifications to the above procedure to permit the determination of sulprofos residues in animal tissues, milk and eggs have been developed. These modifications involve alterations in the initial extraction procedures - using acetonitrile and or hexane instead of acetone and chloroform (Sandie and Gronberg, 1975, MRID GS0076-174).

In addition to the above-noted analytical methods, an interference study has been submitted and reviewed by the Agency. In this study, cottonseed samples were fortified with various pesticides at the tolerance level established for sulprofos. Compounds with zero tolerances were spiked at 0.1 ppm. With the exception of Guthion and its oxygen analogue, interference from these compounds was negligible. The 0.5 ppm Guthion and Guthion oxygen analog spikes produced GLC peaks with the same retention time as the sulprofos (actually, the oxygen analog of the sulfone) and equivalent to 0.07 and 0.11 ppm respectively. These levels are equal to only 14 and 22 percent of the established tolerance and would not interfere with the determination of sulprofos only if the sulprofos was present at levels below its tolerance (Close, C.L., 1975, MRID GS0076-074).

A confirmatory procedure, eliminating any interference from Guthion residues, has been developed. This procedure involves utilizing a GLC column with a different polarity (Close, C.L., 1975, MRID GS0076-076).

In view of those facts presented by the preceeding discussion of analytical methodology, the Agency has determined that the analytical methods are suitable for enforcement of all established tolerances.

VIII. ECOLOGICAL EFFECTS

A. Avian Toxicity
B. Mammalian Toxicity
C. Aquatic Organism Toxicity
D. Nontarget Insect Toxicity

Sulprofos, as noted earlier within the Use Profile section of Chapter V., is a field use insecticide/acaricide applied by either ground or aerial equipment. As a function of both the site and method of application, it may be readily anticipated that some potential for exposure to nontarget terrestrial and aquatic organisms does exist.

A. Avian Toxicity

Sulprofos has been determined to be highly toxic to upland game birds. The LD_{50}, as determined for bobwhite quail, has been calculated to be 47 mg/kg. These same data, subjected to Finney Probit Analysis, have provided an LD_{10} of 24 mg/kg (Fink R., 1979, MRID GS0076-081). In a similar study conducted on mallard ducks, Agency analysis of the data has provided LD_{50} values of 72.1 (43.9-118.4) and 112.2 (87.9-143.2) mg/kg for males and females respectively (Lamb and Jones, 1975, MRID GS0076-119). This latter study, although determined to be only supplemental due to the appearance of several anomalies within the experimental procedure and the data reporting, is being considered as sufficient for an interim determination.

Eight day subacute feeding studies on bobwhite quail and mallard ducks have similarly provided that sulprofos is highly toxic to avian species. The dietary LC_{50} for bobwhite quail, as provided by the data, is 99 ppm. These same data, when subjected to probit anlaysis, have provided an LC_{10} of 63 ppm. The acute dietary toxicity of sulprofos to waterfowl appears somewhat less. The eight day dietary LC_{50} for mallard ducks has been calculated to be on the order of 983 ppm (Lamb and Jones 1975, MRID GS0076-120).

Although acutely toxic, sulprofos does not appear to pose a significant reproductive risk in relation to upland game birds. Sulprofos technical has been found to have no statisticallly significant effect on reproduction when fed to bobwhite quail at dietary levels up to 19 ppm actual (20 ppm nominal) (Fink, R., 1979, MRID GS0076-082). The one-generation reproductive impairment study available for waterfowl has indicated that the no effect level is significantly less than that noted for upland game birds (Wildlife International, Ltd., 1978 MRID GS0076-185). The reproductive impairment NOEL

for the mallard duck is <3 ppm. This latter study, however, has been designated as supplemental data, not fully fulfilling Agency requirements. The Agency shall not, however, identify this study as a data gap within the current standard. These data may, however, be requested should expanded use patterns involve sites of application presenting an increased exposure potential to waterfowl species.

The preceding avian data do indicate that there may be an acute or subacute hazard to certain avian species. The Agency, however, in the absence of field study data, does not have sufficient information with which to assess potential adverse effects which might ensue actual use. Dietary levels resulting from differing treatment methods and regimes must be identified before the Agency may fully delineate sulprofos' potential effects in relation to avian species. See Chapter III for identification of additional study requirements.

B. Mammalian Toxicity

In relation to mammals, the Agency has utilized that data submitted in response to human health effectd data requirements. For a discussion of these data, please refer to Chapter VI.

C. Aquatic Organism Toxicity

With respect to aquatic organisms, sulprofos appears reasonably toxic to both invertebrate and vertebrate species. In two seperate studies, Daphnia magna exhibited pronounced sensitivity with 48 hour EC_{50} values of 0.75 (0.52 - 1.09) and 0.83 (0.69 - 0.99) ppm (Morrissey, A.E., 1979, MRID GS0076-160 and Nelson, D. 1979, MRID GS0076-164). Only data classified as supplemental are available for vertebrate species. These data do, however, point to sulprofos being acutely toxic to fish with 96 hour LC_{50} values of 1.0 (0.7 - 1.5), 2.9 (1.9 - 4.4), and 29.7 (25.4 - 34.6) ppm for the bluegill sunfish, channel catfish and rainbow trout respectively (Lamb and Roney, ?, MRID GS0076-138). The supplemental, rather than valid, classification applied to these data stems, in large part, from the inability of the researchers to render sufficient sulprofos soluble in water. Although these data tend to indicate that sulprofos may present an acute hazard to both vertebrate and invertebrate aquatic species, there remains some question as to the potential mobility of sulprofos and/or its degradation products from sites of application into aquatic environments. As noted within Chapters III and V, the Agency has identified adsorption/desorption data as a data gap. Upon receipt of acceptable adsorption/desorption data, the Agency will be in a position to calculate an estimated environmental concentration (EEC). Should the EEC demonstrate a theoretical potential for the movement of harmful concentrations of either sulprofos and/or its degradation products, the Agency will require both embryolarvae and aquatic field test studies.

D. Nontarget Insect Toxicity

Very limited data are available with respect to sulprofos' acute toxicity to beneficial insects. Those data that are available, however, provide that sulprofos, like most organophosphate pesticides, is toxic to the honey bee (Johansen et al., 1975, MRID GS0076-101). Although these data are limited, they appear adequate in relaton to current hazard labeling needs. Additional study requirements may, however, be necessitated by the addition of critical sites of application to the labeling and upon the promulgation of Subpart L of the Guidelines.

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. 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. 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, (2) citations in numerical order that have been examined and judged to be inappropriate for use in developing the standard.

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 ALPHABETICAL BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Standard

CASE GS0076 Sulprofos

MRID CITATION

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