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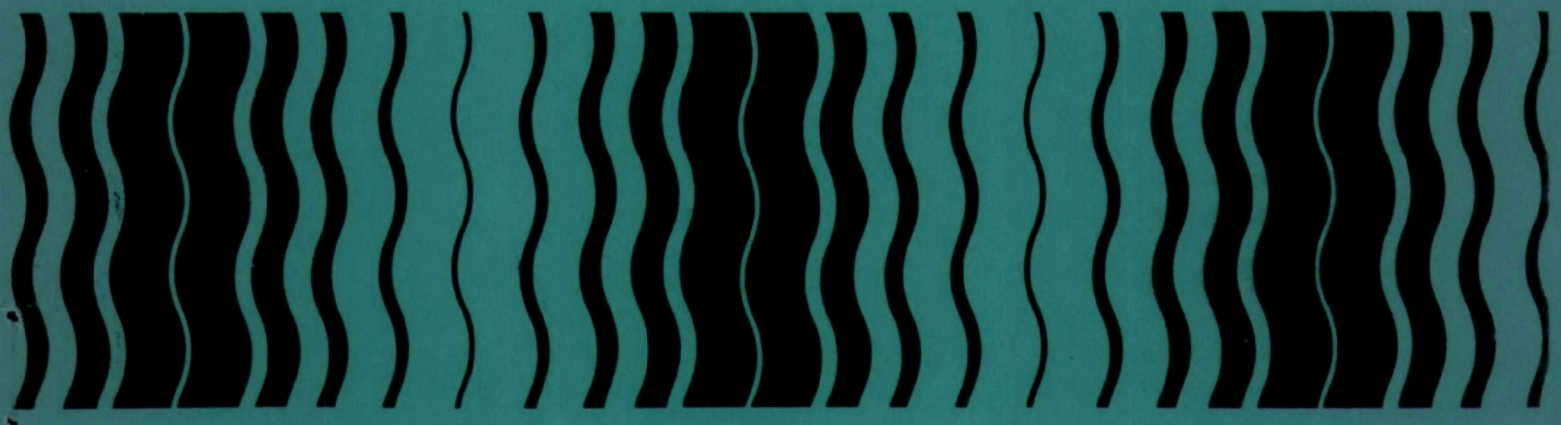
Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing Brominated Salicylanilide as the Active Ingredient



GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

AS THE ACTIVE INGREDIENT

BROMINATED SALICYLANILIDE

CASE NUMBER 0347

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in unreasonable adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available from the National Technical Information Service, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers

of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA may issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of an product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, <u>will</u> be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the <u>requirements in I-A and B.</u>

I. REGULATORY ASSESSMENT

A. INTRODUCTION

Registration standards describe the regulatory position and rationale for all registered manufacturing-use products (MUPs) containing the chemical under review as the sole active ingredient. Normally end-use products (EUPs) are reviewed only when there are no MUPs registered or when EPA determines that significant changes apply to end-use products. In the case of the brominated salicylanilides (also known as bromosalans) the Agency anticipated that it would be more efficient to address both end-use products and manufacturing-use products at the same time. The three chemicals in this group, 3,4',5-Tribromosalicylanilide (3,4',5-TBS), 3,5-Dibromosalicylanilide (3,5-DBS), and 4',5 Dibromosalicylanilde (4',5-DBS) are related chemically, have similar toxicological concerns, and are found in combination with one another in a wide variety of products.

1. Manufacturing-Use Products (MUPs)

There are two MUPs containing 3,4',5-TBS in combination with small amounts of 3,5-DBS and/or 4',5-DBS, but there are no MUPs for the technical grade of 4',5-DBS or 3,5-DBS. There is one MUP which is a 45/45 mixture of 3,4',5-TBS and 4',5-DBS.

2. End-Use Products (EUPs)

There are forty-seven EUP's Federally registered for use in all states (interstate) and five EUP's registered for use only within one specific state (intrastate). Some of these are single active ingredient products but the majority are multiple active ingredient products containing, in addition to combinations of the bromosalans, phenolic or quaternary ammonium germicides.

Future requests for registration of substantially similar products will be considered under this standard. Dissimilar products will be evaluated on a case by case basis; if they are registered the Agency will amend the standard accordingly. After briefly describing the chemicals and their uses, this chapter presents the regulatory position and rationale, the criteria for registration, acceptable ranges and limits, and labeling considerations.

In developing its regulatory position, the Agency determines whether available data indicate that a pesticide has met or exceeded the criteria for unreasonable adverse effects specified in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR). Pesticides meeting these critieria are candidates for a Special Review, an intensive risk/benefit analysis. The Agency's determination as to whether any criteria have been met and its rationale for any regulatory action are summarized in the regulatory position of this standard.

B. DESCRIPTIONS OF THE CHEMICALS AND THEIR USES

1. Chemical and Physical Characteristics

The brominated salicylanilides also known as bromosalans are normally derived from salicylic acid usually in a reaction with aniline in the presence of phosphorus trichloride in a diluent (The Merck Index, 9th Ed. 1976). Bromination is the final step in this synthesis. The molecular weight of 3,4',5-TBS is 449.96; for 3,5-DBS and 4',5 DBS, it is 371.03. 3,4',5-TBS is an odorless, colorless white powder with a melting point of 227-228°C. The samples which were evaluated under this standard had an approximate melting point of 214-226°C varying presumably with the samples' purity. 3,4',5-TBS is soluble in methanol, ethanol, isopropanol, ethyl ether and benezene (0.5-4.0%); sparingly soluble in chloroform and cyclohexane (0.01-0.5%); insoluble in water and petroleum ether.

The bromosalans are used as antimicrobials and fungicides. 3,4',5-TBS is sold under the trade name Tempasept and is also referred to as Tribromsalan. The Chemicals Abstract Service (CAS) Registry Number is 87-10-5 and the EPA/OPP Pesticide Chemical Code No. is 077404. 3,5-DBS has a CAS No. of 2577-72-2 and an EPA/OPP No. of 077405. 4',5-DBS has a CAS No. of 87-12-7 and an EPA/OPP No. of 077402.

2. Registered Uses

The primary registered uses for the bromosalans are as germicides for nonfood contact hard surfaces and equipment in commercial and industrial areas, eating establishments, homes and hospital premises; as fungicides for the control of mold and mildew in bathrooms, schools, homes and hospitals; and as antimicrobial preservatives in laundry additives, textiles, manufactured products, and exterior latex paints. There are no registered uses of the bromosalans involving direct application to agricultural crops or to food or feed.

C. REGULATORY POSITION AND RATIONALE

Data are lacking to fully assess the registered uses of the bromosalans. Based on the review and evaluation of what little data are available and other relevant information on the bromosalans, the Agency has made the following determinations.

1. Risk Criteria Assessment

There are no data available to the Agency to establish whether or not the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the registered uses of the bromosalans. Hence registrants must submit a substantial amount of data as specified in the data tables of this document.

Rationale

Part of the registration standard process is to re-evaluate available data on the active ingredient(s) to determine whether such data will continue to support the registered uses without unreasonable adverse effects on humans and the environment and thus determine whether the risk criteria of §162.11(a) of 40 CFR have been met or exceeded. In those instances where there are no data available to make this determination, the Agency identifies the required data and allows reasonable time to provide the data to make such a determination.

2. Human Toxicity Concerns

(a) Manufacturing-Use Products

To maintain current registrations as well as register new products or reregister currently registered products, the data specified in the Table A and Table B toxicity data requirements must be submitted. This would initially consist of the basic acute labeling and user protection data, teratology studies, a 21-day subchronic dermal study, and a mutagenic battery for the technical grade of each active ingredient. For those products used as textile biocides, exposure, leachability, and dermal penetration studies will also be required.

(b) End-Use Products

Registrants of EUPs covered under this standard will be required to submit the product specific acute toxicity data specified in the Table C toxicology requirements.

Rationale

There are no toxicity data available for the manufacturing-use product containing bromosalans. Since the uses of the bromosalans as household and hospital disinfectants may result in repeated dermal exposure, teratology, 21-day subchronic dermal, and mutagenic studies are being required in addition to the basic acute studies. A requirement to develop long-term chronic toxicity data is being reserved pending the results of these studies.

The three bromosalans also have varied uses which would be covered by the proposed policy for registration of textile biocides as published in the Federal Register, Vol. 47, No. 240, pp 55967-55970, December 14, 1982. For those uses exposure estimates or determinations must be submitted to demonstrate what exposure is likely or not likely to occur under the conditions of use. These estimates may be based on actual studies or on scientific rationale.

If the intended uses as textile biocides have the potential for direct body contact, then leachability studies from different fabrics (e.g. cotton, synthetics) via perspiration, urine, laundry washing, dry cleaning, and effect of pH are required. These studies should be performed with a typical pesticide formulation - i.e. an end use product not on three different technical grade chemicals - containing all three active ingredients preferably at the highest percent allowed on any product that bears labeling for use as a textile biocide. If any of the three active ingredients leaches in any amount, then a determination of the dermal penetration of that ingredient using a radiolabeled mixture must be conducted. If there is no leaching, then a request for a waiver of the penetration studies would be appropriate.

Protocols for determining exposure, leachability, and dermal penetration must be submitted to the Agency for review, prior to the initiation of these studies, no later than 120 days from the date of this standard, and the actual data must be submitted no later than 12 months from the date of notification by the Agency to proceed with the studies.

Since the EUPs addressed by this standard contain a wide variety of active and inert combinations and data on one formulation cannot be extrapolated to support another formulation, product specific acute toxicity data will be required for each product covered by this standard.

3. Exposure Assessment Concerns

(a) Manufacturing-Use Products

Data on hydrolysis and photodegradation in water are required for the technical grade of each active ingredient.

(b) End-Use Products

No product specific environmental fate data will be required.

Rationale

There are no environmental fate data available for the bromosalans. Based on the registered uses of these products as disinfectants, laundry additives, textile preservatives, and manufactured products, discharge of these chemicals into public waters, lakes, and streams is possible.

Therefore, the Agency requires these data to evaluate the type and persistence of residues of these chemicals in the aquatic environment.

Environmental Fate data on the end-use product are only required if any of the registered uses will cause additional exposure concerns to non-target organisms which cannot be assessed by data developed on the technical grade of the active ingredient. This is not the case with any of the registered uses of the bromosalans.

4. Groundwater Contamination

There is a possibility of contamination of groundwater by the bromosalans.

Rationale

Even though all the registered uses covered by this standard are indoor, due to the nature of these uses as noted under (C)(3) above, groundwater contamination is possible. The submission of the required environmental fate data for the technical grade of the active ingredient will enable the Agency to more fully address this issue.

5. Ecological Effects Concerns

(a) Manufacturing-Use Products

An avian dietary LC_{50}, a freshwater fish LC_{50}, and a freshwater invertebrate LC_{50} will be required for the technical grade of each active ingredient.

(b) End-Use Products

No product specific fish and wildlife data will be required.

Rationale

There are no fish and wildlife data available for the bromosalans. As noted above under (C)(3), the registered patterns of use are such that these chemicals may be discharged into the environment. While the production of this material is small and the possibility of exposure is limited, a minimal amount of fish and wildlife data is necessary to assess the potential hazard of these chemicals.

Fish and Wildlife data on the end-use product are only required if any of the registered uses will cause additional exposure concerns to non-target organisms which cannot be assessed by data developed on the technical grade of the active ingredient. This is not the case with any of the registered uses of the bromosalans.

6. Endangered Species Consideration

The bromosalans should not pose a hazard to endangered species.

Rationale

All the uses covered by this standard are indoor.

7. Product Chemistry Concerns

(a) Manufacturing-Use Products

To register new products, the data specified in the Table A and Table B product chemistry data requirements must be submitted.

In addition to the requirements of 40 CFR 158.120, the following additional information is required to supplement the manufacturing procedure required for the technical grade of 3,4',5-TBS, 3,5-DBS, and 4'5-DBS.

- A statement of whether the process is a batch or continuous process.
- The composition of the beginning materials and order in which they are added.
- A description of the equipment used to produce the product which may influence the product's composition.
- A description of the physical conditions which are controlled during each step of the process in order to influence the product's composition.
- A flow chart listing chemical equations of each chemical reaction.
- The duration of each step of the process.
- A description of any purification procedures.
- A description of quality control measures.
- An indication of whether or not the registered technical or manufacturing use products are the products of synthesis and/or blending.

(b) End-Use Products

Each EUP covered under this standard will be required to submit the product specific basic chemistry data specified in the Table C product chemistry data requirements.

Rationale

The available product chemistry data are insufficient to satisfy the basic chemistry data requirements for the bromosalans. This consists of an out-of-date 1959 description of the manufacturing process submitted for 3,4',5-TBS,[1]/ and data on the physical and chemical properties of "essentially pure" 3,4'5-TBS, containing about 5% 3,5-DBS and essentially free of 4'5-DBS[2]/. No data are available for the technical grade of 3,5-DBS and 4',5-DBS.

Discussion of the formation of impurities has not been provided nor is there any up-to-date information available on the preliminary analysis of commercially available chemicals. For the technical grade of each active ingredient, a discussion addressing the impurities likely to be present in amounts of 0.1% or more and the highly toxic impurities which may be present in any amount is required.

Since the EUPs addressed by this standard contain a wide variety of active and inert combinations, product specific basic chemistry data will be required for each product covered by this standard.

D. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be registered under this standard, products must contain either 3,4',5-TBS, 3,5-DBS, or 4',5-DBS or combinations of these ingredients as active ingredients, conform to the product composition, acute toxicity limits, use pattern requirements, and the required labeling as prescribed in various sections of this standard, in addition to those prescribed in Section F of this chapter.

1/ Hexcel Corporation MRID No. 00043906
2/ Dow Chemical Company MRID No. 00042949

Applicants for registration or reregistration and registrants of products under this standard who wish to maintain their registrations in effect before reregistration must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, and a commitment to fill data gaps and where applicable pay compensation as required by FIFRA Sections 3(c)(1) and 3(c)(2) on the schedule specified in this document.

Registrants of end-use products who do not qualify for the Formulator's Exemption must satisfy labeling, packaging and data requirements in accordance with this guidance package.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition

(a) Manufacturing-Use Product

The technical grade of 3,4',5-TBS has been defined by this standard as material containing at least 95% 3,4',5-TBS, 5% 3,5-DBS, and essentially free of 4,5-DBS. Applicants who wish to register a technical grade of 3,4',5-TBS differing in composition from this material must satisfy whatever additional data requirements apply to such modifications. If such products are registered the Agency will amend the standard to include such products.

No information is available for the technical grade of 3,5-DBS or 4',5-DBS. Applicants who wish to register, under this standard, pesticide products containing these chemicals must submit the product chemisty data as discussed under (C)(7) above and satisfy all other requirements for technical grade and manufacturing-use products discussed elsewhere in this document.

(b) End-Use Products proposed for registration under this standard must be substantially similar to the products listed in the EPA Index to Pesticide Chemicals which lists the formulations approved for the brominated salicylanilides. A product will be considered substantially similar to a registered product if it contains the same active ingredients at approximately the same concentrations.

2. Acute Toxicity Limits

(a) Manufacturing-Use Products

The Agency will consider registration or re-registration of technical grade products and manufacturing-use products containing 3,4',5-TBS, 3,5-DBS, or 4',5-DBS for any proposed acute toxicity categories, provided that the registrant submits the data necessary to establish the toxicity category for each route of exposure, thereby permitting the Agency to prescribe appropriate precautionary statements consistent with 40 CFR §162.10.

(b) End-Use Products

The Agency will consider registration or re-registration of end-use products containing 3,4',5-TBS, 3,5-DBS, or 4',5-DBS provided that acute toxicity data specific to the particular end-use product is submitted. This is required to establish the acute toxicity categories for those potential routes of exposure, and thus enable the Agency to prescribe appropriate precautionary statements in accordance with Section 162.10 of 40 CFR.

3. Use Patterns

(a) Manufacturing-Use Products

To be registered under this standard, MUPs must be labeled for formulation or repackaging as disinfectants, sanitizers, fungicides, preservatives, or additives for the control of the pests listed in the EPA Index to Pesticide Chemicals which lists the uses, sites, and pests which have been approved for the brominated salicylanilides.

(b) End-Use Products

EUPs can be registered under this standard if the proposed uses, sites, and pests have been previously accepted. For a use not covered under this standard, the applicant must submit all data necessary for EPA to determine whether to approve the application. If the application is approved, EPA will issue a supplement to the standard.

F. REQUIRED LABELING

All manufacturing-use pesticides and end-use pesticides must bear appropriate labeling as specified in the general labeling requirements of Section 162.10 of 40 CFR. For more details on these requirements see Chapter V and Appendix IV-1 of this standard. The following specific requirements apply to the labels for the brominated salicylanilides.

1. Ingredient Statement

The ingredient statement for manufacturing-use pesticides and end-use pesticides must appear on the front panel as follows:

ACTIVE INGREDIENTS
(Name of Ingredient)..... %
(Name of Ingredient)..... %
INERT INGREDIENTS..... %

2. Use Patterns

The label for all manufacturing use products must state that they are intended for formulating or repackaging pesticides which must be registered for the sites and pests listed in the EPA Index to Pesticide Chemicals. A limiting factor will be data that support these use patterns. No use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A, Table B or Table C of this standard for that use pattern. Labels for MUPs are not required to bear complete directions for use of the pesticide. They are required to comply with the labeling requirements of Section 162.10(i)(1)(iii) of 40 CFR.

3. Precautionary Statements

(a) Manufacturing-Use Products

(i) Labels for all manufacturing-use products containing a brominated salicylanilide must bear statements reflecting the product's acute human toxicity as explained previously in Section E(2)(a) of this chapter.

(ii) The following environmental hazard statement must appear on the label of all MUPs, under the required heading as designated below:

ENVIRONMENTAL HAZARDS

"Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES[1]/ permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA".

1/ National Pollution Discharge Elimination System

(iii) Depending on the results of the ecological effects data required to register the MUP, the label may require a fish and/or wildlife hazard statement, as specified in Section 162.10(h)(2)(ii) of 40 CFR. For the data requirements see Table A, Generic Data Requirements.

(b) End-Use Products

Labeling for each end-use product must bear appropriate precautionary statements specific for the product as formulated. These statements must reflect the acute toxicity categories established by data relevant to the particular product in question, in accordance with Section 162.10 of 40 CFR. For the data requirements see Table C, Product Specific Data Requirements.

G. TOLERANCE REASSESSMENT SUMMARY

No data are required to establish a tolerance or an exemption from the requirement of a tolerance.

Rationale

The registered uses for the bromosalans are not likely to result in residues in food or feed, hence no data are required to establish a tolerance or an exemption from the requirement of a tolerance.

Registrants who propose such uses must satisfy the data requirements to establish a tolerance. If the tolerance is established the Agency will amend the standard accordingly.

H. INCIDENTAL FOOD ADDITIVE ASSESSMENT

Products containing the bromosalans (i.e. bromosalicylanilides) will not be registered under this standard for use as a terminal sanitizing rinse on food contact surfaces in establishments engaged in processing or preparing food for consumption by the general public, unless they are cleared for this use in accordance with the provisions of Section 178.1010 of Title 21 of the Code of Federal Regulations within a year of the date of issuance of this standard.

Rationale

Antimicrobial agents which are recommended or sold to control the growth of microorganisms of public health concern on inanimate surfaces are defined as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and, therefore, must be registered with

the Environmental Protection Agency (EPA). However, pesticides recommended for this use are also identified as incidental food additives under the Federal Food, Drug, and Cosmetic Act (FFDCA) and, therefore, must comply with the regulations at 21 CFR §178.1010, governing sanitizing solutions, which are administered by the Division of Food and Color Additives of the Food and Drug Administration (FDA).

The Food and Drug Administration exercises authority over establishments which are engaged in the business of processing or preparing food for consumption by the general public, such as restaurants, food processing plants, dairies, soft drink plants, breweries, etc. To ensure that food processed or prepared in such establishments is not contaminated with microorganisms which may be injurious to the public, the FDA requires that food processing equipment, utensils, and food contact surfaces be precleaned and washed to remove gross filth and food particles, rinsed with water to remove traces of detergent, and rinsed with a terminal sanitizing solution.

Such solutions may only contain antimicrobial agents and other chemical ingredients at specified concentrations as approved at Section 178.1010 of 21 CFR; and treated utensils, equipment, and surfaces must be allowed to dry adequately by drainage (air dried) before they are used.

Products which are now being used or recommended as sanitizing solutions to treat food contact surfaces, and which bear label recommendations to follow such treatment with a potable water rinse negate the purpose and intent of the treatment and will no longer be allowed. Furthermore, a potable water rinse may recontaminate the sanitized surfaces with bacteria which may be present in the water, thus introducing a risk to public health. Hence, the use of an antimicrobial at the sanitizing level of activity on food contact surfaces is defined as a terminal sanitizing rinse; and although the EPA has approved antimicrobial labels for this use in the past with a potable water rinse recommendation, such labels will no longer be approved.

I. EFFICACY EVALUATION SUMMARY

No product specific microbiological efficacy data were evaluated for the bromosalans.

Rationale

The only data normally required by the Agency for manufacturing-use products which are to be reformulated into antimicrobials is presumptive evidence of their effectiveness. Since the bromosalans have been widely used as antimicrobials for many years, this presumptive evidence has already been established and no data will be required for MUP's.

Nor will efficacy data be required for products bearing claims for effectiveness against microorganisms of economic or aesthetic significance. Such claims are defined as non-health related and the Agency has waived product performance data for these uses.

Section 162.18-2(d)(2) of 40 CFR requires that "efficacy data specific to each product that bears a claim to control organisms that may pose a threat to human health, either directly or through transmittal of disease" must be submitted to support the registration of such a product. Each antimicrobial product intended to control microorganisms infectious to man in any area where these microorganisms may present a health hazard falls under the requirement of this section. Microbiological efficacy data are product specific; data for one product can not be used to support registration of another product unless the two products are identical. Even then confirmatory data is required to register a product relying on data developed with another product.

The specific data requirements for end-use products intended to provide health related benefits and the conditions under which the Agency will evaluate previously submitted efficacy data are explained in the Standard Efficacy Chapter which directly follows this section.

STANDARD EFFICACY CHAPTER - REGISTRATION STANDARDS

ANTIMICROBIAL AGENTS

GENERAL CONSIDERATIONS

Section 3 (c)(5)(D) of the Act provides that the Administrator may waive data requirements pertaining to efficacy of a product under consideration for registration, and hence by inference reregistration, and that if he waives the requirement for data, he may also waive the finding of efficacy required by FIFRA section 3(c)(5)(A). A selective waiver of data by the Administrator has been adopted for non-human-health related pesticides as Agency policy in order to relieve the internal resource burden associated with the review of product performance data. In addition, the selective waiver of efficacy data has been implemented in response to the intent of Congress to reduce the regulatory burden of the affected industry.

It must be clearly understood, however, that the Agency shall continue to expect all registrants to perform those studies necessary to assure that non-human health related products entering the marketplace will perform their intended function(s) when applied in accordance with label directions and commonly accepted pest control practices. While relying upon the integrity of the industry, the Agency does anticipate occasional imperfections in the marketplace self-regulation. The Agency, in this regard shall assume a conditionally passive stance; maintaining a passive role until such time as monitoring or in-house technical expertise triggers a potential efficacy problem. Upon analysis of the validity and impact of the issue, the Agency may choose to remain passive, adopt a market assistance posture, or adopt a presumptive posture dependent upon the product attributes or the nature and significance of the concern. To this end, the Administrator shall reserve the right to request submission of efficacy data in support of label claims for any registered product. A request, under the authority of 3(c)(2) (B), may be made for any product for which a pattern of inadequate performance has been reported. Should such a request be tendered, the request may be satisfied through the submission of data developed in accordance with the Pesticide Assessment Guidelines, Subdivision G, Product Performance, Series 91: Efficacy of Antimicrobial Agents, Subseries 91B: NON- PUBLIC HEALTH USES, EPA Document Number 540/9-82-026, November 1982 available from the National Technical Information Service, Springfield, VA, NTIS Order No PB 83-153924.

Other regulatory considerations that must be noted for non-health related antimicrobial pesticides include:

1. FDA Regulations at 21 CFR 173.320 for antimicrobial agents used in sugar mills.

2. FDA Regulations at 21 CFR 176.300 for slimicides used in the manufacture of paper and paperboard that contact food.

3. FDA Regulations at 21 CFR 175.105 for preservatives used in adhesives intended for use in the packaging of food.

4. FDA Regulations at 21 CFR 173.315 for chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

5. Fuel Additives:

   (A) If the use is for aviation fuel, clearance is required from the Federal Aviation Administration.

   (B) If the use is for motor vehicle gasoline, diesel fuel, or engine oil, the product must be registered with the Office of Fuel and Fuel Additive Registration, EPA.

The Agency, in response to public comment and internal deliberation, has limited its direct area of concern to, and shall maintain a continuing efficacy data submission requirement for certain health-related use patterns. With respect to registration, the Agency will require product performance data in support of public health uses. A public health use exists whenever the continued presence of a target pest organism may pose a threat to health, either by direct action or through transmittal of disease. The definition for public health uses shall be further limited to include only those uses for which the Agency believes there are inadequate marketplace controls, and for which there appears to exist a low order of user recognition of product performance. Such uses include antimicrobial use patterns. Performance data will be required for all antimicrobial products intended to control microoganisms infectious to man in any area where these microorganisms may present a health hazard.

The following criteria will be utilized to determine whether or not the labeling of an antimicrobial pesticide bears uses of human health/public health significance:

PUBLIC HEALTH SIGNIFICANCE/SUPPORTING DATA REQUIRED:

1. Products bearing claims for control of microorganisms infectious for man will be considered as directly related to human health and will require specific and complete efficacy data to support such claims and patterns of use.

2. Unqualified and non-specific claims for products as sterilizers, disinfectants, or sanitizers will be considered to include or imply effectiveness against microoganisms infectious for man. Antimicrobial products recommended for use in hospital or medical environments, including sickrooms in public or private dwellings, will be similarly considered as human-health-related, and efficacy data will be required.

3. Hospital sterilizers and disinfectants, swimming pool water disinfectants, human drinking water disinfectants and purifiers, and food-contact surface sanitizers are, by their very nature, human health-related and will require efficacy data whether or not control of specific infectious microorganisms are claimed.

4. Veterinary and animal premise disinfectants will require efficacy data to support claims against those microorganisms which are infectious for both man and animals.

NON-PUBLIC HEALTH SIGNIFICANCE/NO SUPPORTING DATA REQUIRED:

1. Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health will not require efficacy data.

2. Products bearing claims for effectiveness at the bacteriostatic level (inhibition of growth) are not acceptable for health-related use patterns. Bacteriostatic claims are only permitted for products.

expressly recommended for control of microorganisms of economic or aesthetic significance, not directly related to human health and therefore, will not require efficacy data. (e.g. slime-forming bacteria, odor-causing bacteria).

3. Veterinary and animal premise disinfectants will not require efficacy data for claims against micro-organisms which are infectious only for animals.

4. Manufacturing use products for the formulation of antimicrobial pesticides only, will not require efficacy data unless end-use recommendations are made (dosages; claims; recommended formulations).

SPECIFIC CONSIDERATIONS

I EFFICACY DATA NOT REQUIRED:

Those patterns of use recorded upon current labeling for products containing brominated salicyanilide as the active ingredient, that fall within the non-human health-related use category for which efficacy data submission and review are waived, need not be supported by efficacy data submission or reference.

EFFICACY DATA REQUIRED:

II Those patterns of use recorded upon current labeling for products containing brominated salicyanilide as the active ingredient that fall within the non-waivable, human health-related use category must be supported by efficacy data submission.

Section 162.18-2(d)(2) of 40 CFR requires that "efficacy data specific to each product that bears a claim to control organisms that may pose a threat to human health, either directly or through transmittal of disease" must be submitted to support the registration of such a product. Each antimicrobial product intended to control microorganisms infectious to man in any area where these microorganisms may present a health hazard falls under the requirements of this section. Microbiological efficacy data are product specific; data for one product can not be used to support registration of another product unless the two products are identical in composition, use pattern, claims, dosages. Even then, confirmatory data is required to register a product relying on data developed with another product. The Agency has determined that the nature of these products is such that performance is intimately linked to and dependent upon not only the final concentration of identified active ingredients, but also the inert constituents of the complete formula, the manufacturing process, raw material quality, etc. It is for these reasons that formulation specific efficacy data must be demanded for each product proposed for reregistration. Such data shall be submitted for review at the time of submission for reregistration.

The specific, current efficacy data requirements (test methodology and performance criteria) for end-use products intended to provide human health-related benefits can be found in the guidelines for product performance:

Pesticide Assessment Guidelines
Subdivision G, Product Performance, Series 91:
Efficacy of Antimicrobial Agents, Subseries 91A,
Public Health Uses
Available from National Technical Information
Service, Springfield, VA 22161
EPA Document Number 540/9-82-026, November 1982
Order No. PB 83-153924

Other regulatory considerations that must be noted for health-related pesticides include:

Products proposed for use as final sanitizing rinses on food contact surfaces, food handling equipment, and eating utensils in food processing establishments, must comply with FDA Regulations at 21 CFR 178.1010.

2. Products recommended for use in federally inspected food processing plants must be authorized for such use under the USDA (U.S. Department of Agriculture) Inspection and Grading Program.

3. Products recommended for use on certain medical devices, such as hemodialysis equipment, are also required to be approved by the Office of Device Evaluation, Center for Devices and Radiological health, FDA.

4. The new use of an active ingredient for sanitization of hatching eggs may require approval as a new animal drug by the Bureau of Veterinary Medicine, FDA.

5. Products recommended as sanitizers for food grade eggs must meet the same criteria as for use on food contact surfaces, FDA Regulation at 21 CFR 178-1010.

Additional specific guidance is available concerning current efficacy data requirements in the DIS/TSS Enclosures listed below and available from the Disinfectants Branch, Registration Division:

1. Efficacy Data Requirements - Disinfectants

2. Efficacy Data Requirements - Supplemental Recommendations

3. Efficacy Data Requirements - Reporting of Data

4. Efficacy Data Requirements - Sanitizing Rinses(for previously cleaned food-contact surfaces)

5A. Confirmatory Data Requirements - Duplicated product formulations.

5B. Confirmatory Data Requirements - Product formulations identical to a registered product. Formulations produced by simple dilution of registered concentrates.

6. Efficacy Data Requirements - Supplemental Efficacy

7. Efficacy Data Requirements - Virucides

8. Efficacy Data Requirements - Carpet Sanitizers

9. Efficacy Data Requirements - Sterilizers

10. Efficacy Data Requirements - Sanitizer Test (for inanimate, non-food contact surfaces).

11. Efficacy Data and Labeling Requirements - Air Sanitizers

12. Efficacy Data Requirement - Swimming Pool Water Disinfectants.

13. Efficacy Data Requirements - Laundry Additives/ Disinfection and Sanitization.

14. Efficacy Data Requirements - Laundry Additives/Residual Self-Sanitization and Bacteriostasis.

Efficacy Data Requirements - Pre-saturated or Impregnated Towelettes for Hard Surface Disinfection.

Efficacy Data Requirements - In-Tank Sanitizer Products

Testing Requirements for Alkaline Glutaraldehyde Products

Reuse Testing of Sterilant/Disinfectant Solutions

Efficacy Data Requirements - Water Purifier Units

Efficacy Data Requirements - Emergency Water Supplies

EFFICACY DATA SUBMISSIONS FOR REREGISTRATION

Over the past several years, products relying on basic efficacy data developed prior to revision of the efficacy data requirements were permitted to retain label claims and registration, in certain situations. However, registrants were informed that at the time of reregistration compliance with the updated efficacy data requirements would be required.

Therefore, for reregistration, only efficacy data developed in accordance with the current data requirements expressed in the Pesticide Assessment Guidelines and the DIS/TSS Enclosures will be considered for review in support of reregistration.

If efficacy data meeting the current requirements has been previously submitted, assigned an Accession Number, been reviewed, and accepted, the application for reregistration should identify the Accession Number, Date of Submission, Title of Study and Laboratory who conducted the study.

If previously submitted efficacy data does not meet the current requirements, it will not be considered in support of reregistration and should not be submitted. New efficacy data, developed according to current requirements must accompany the application for reregistration.

a077402 4',5-DIBROMOSALICYLANILIDE
and
a077404 3,4',5-TRIBROMOSALICYLANILIDE
and
a077405 3,5-DIBROMOSALICYLANILIDE
and
OTHER ACTIVE INGREDIENTS

TYPE PESTICIDE: Antimicrobial, Fungicide

FORMULATIONS:
FI (90%, 99%, 100%)
Impr (0.2%)
SC/S (0.15%, 0.6%, 79%, 99%)
SC/L (0.02%, 0.1%, 0.25%, 2%, 3%, 3.1%, 3.11%, 6.2%)
RTU (0.05%, 0.2%, 5%, 10%, 15%, 100%)
PrL (0.0014%, 0.0134%, 0.02%, 0.025%, 0.05%, 0.2%, 0.36%, 0.7%, 1%)

PRESENTATION OF INFORMATION: All final concentrations are expressed in parts per million (ppm) total active ingredient(s) or ppm available quaternary ammonium compound. Concentrations are rounded to the nearest whole number when the value is less than 1,000 and to the third significant figure when the value is greater than 1,000. Unless otherwise stated, the dilutions are the ratio of the volume of the product to be diluted to the volume of fluid in which the product is diluted. The dilutions are rounded to the nearest whole number. In some instances, dosages are given as weight of product based on the total weight of the material being treated.

When bromosalicylanilides are formulated with quaternary ammonium compounds or other active ingredients, separate ppm calculations are given in the following order: 1) bromosalicylanilides, 2) quaternary ammonium compounds, and 3) other active ingredients.

GENERAL WARNINGS AND LIMITATIONS: For claims/uses against microorganisms of significance for human health, efficacy data is formula specific (including inerts) and cannot be extrapolated.

Refer to individual sites for general warnings and limitations that are specific for that particular site.

Do not mix any product containing a quaternary ammonium compound in its formulation with soaps or anionic detergents as these mixtures will reduce the effectiveness of the product. Products containing quaternary ammonium compounds should ot be mixed with other chemicals, particularly oxidizing agents such as chlorine, since such mixtures can form potentially explosive compounds. Hard water may reduce the effectiveness of products containing quaternary ammonium compounds.

Phenolic products should not be mixed with anything but water. For best results, add water to the product.

Note all cautions concerning products under pressure. Do not puncture or incinerate containers. Do not use near heat or open flame. Do not expose to temperature above 120 F (48.9 C).

GENERAL WARNINGS AND LIMITATIONS (continued)

Apply product only as specified on the label and technical data sheets.

Read labels very carefully for specific warnings, human toxicity statements, and environmental cautions.

Follow label directions for the disposal of the product container when empty.

Definition of Terms:
a.i. - active ingredient
ppm - parts per million
quat - quaternary ammonium compound

	Site, Efficacy, Dosage and Formulation	Use Directions
	AQUATIC NON-FOOD	
	(Aquatic Sites)	
/65011MB-2	Swimming Pool Related Surfaces, Shower Rooms and Locker Rooms	
		General Instructions for Use The products registered in this site are intended for use on locker room, shower room, and swimming pool related surfaces. Swimming pool related surfaces include bathhouse surfaces, diving boards, ladders, poolside surfaces, runways, walkways, and other areas around swimming pools commonly contacted by bare feet. Precleaning of surfaces to remove soil and filth deposits is usually recommended. Observe required contact time. Apply solutions to surfaces by mop, swab, spray, or brush.
A24	Bacteriostat	
	348 ppm 347 ppm (3% SC/L)	Bacteriostatic treatment for surfaces. Formulated with N-lauryl diethylenetriamine.
A22 A24 FYABQBB	Disinfectant Deodorizer Mold/mildew	
	450 ppm 1,500 ppm (0.045% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol and 4-chloro-2-cyclopentylphenol.

	Site, Efficacy, Dosage and Formulation	Use Directions
	INDOOR	
	(Pets and Domestic Animals) (Animals and Their Man-made Premises)	
/53010GA	Fishing Equipment	General Instructions for Use: The product registered in this site is for use on fishing equipment. Spray with product from a distance of 6 to 8 inches for 3 seconds until surface is wet. For mold/mildew control, preclean surface and repeat application weekly.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2 virus	
FYABQBB	Mold/mildew	
	3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on equipment. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.
/54000JA-1	Kennels and Pet Animal Quarters	General Instructions for Use: The products registered in this site are for use in cat, dog, bird, rodent, fish, amphibian, and reptile living and sleeping quarters, equipment, and litter trays. All surfaces must first be cleaned of gross filth and used litter by scrubbing with soap or detergent, followed by a clear water rinse. The diluted or full strength product is then applied to surfaces by mop, spray, scrub, or brush. Allow treatment to dry. Feeding and watering equipment must be thoroughly rinsed with potable water prior to reuse. Kennels and quarters should be thoroughly ventilated before animals are returned to them. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.

	Site, Efficacy, Dosage and Formulation	Use Directions

Kennels and Pet Animal Quarters (continued)

A18	Pseudomonacide
A19	Tuberculocide
A22	Disinfectant
A24	Deodorizer
A25	Virucide-effective against Influenza Type A2 virus
A29	Fungicide
FYABQBB	Mold/mildew

14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
2,000 ppm 2,500-5,000 ppm quat 445,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
2,000 ppm 2,500-5,000 ppm quat 412,000-628,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.

(Household)

/630000A Household Premises and Equipment

General Instructions for Use: The products registered in this site are for use in household premises (i.e. walls, floors, fixtures) and contents (i.e. furnishings, equipment, and other hard surfaces).

Preclean surfaces prior to treatment when required. Dilute products as specified on labels. Apply by mop, wipe, scrub, or spray.

For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Household Premises and Equipment (continued)	
A24	Bacteriostat	
	76-227 ppm (0.25% SC/L) or 500 ppm (0.05% RTU)	Bacteriostatic treatment for surfaces.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2 virus	
A29	Fungicide	
FYABQBB	Mold/mildew	
	76-227 ppm (0.25% SC/L)	Disinfection and mold/mildew control on surfaces.
	14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
	134 ppm 1,000 ppm quat 450,000 ppm (0.0134% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14), and triethylene glycol.
	200 ppm 3,800 ppm (0.02% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol, 4-chloro-2-cyclopentylphenol, and lauryl diethanolamide.
	500 ppm 1,500 ppm (0.05% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol.
	2,000 ppm 2,500-5,000 ppm quat 445,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).

Site, Efficacy, Dosage and Formulation	Use Directions
Household Premises and Equipment (continued)	
2,000 ppm 2,500-5,000 ppm quat 445,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
/630090A **Sickroom Premises and Contents**	General Instructions for Use: The products registered in this site are for use in sickrooms found in places other than primary health care facilities. This includes household, commercial, institutional, and industrial establishments. The products may be used on premises (i.e. ceilings, fixtures, floors, walls, woodwork); contents (i.e. bedding, furniture, telephones); equipment (i.e. basins, bedpans, receptacles, vomitus pails, pans); and utensils (i.e. dishes, trays, eating utensils, glassware). Thoroughly preclean and rinse surfaces prior to treatment. One-step cleaner-sanitizers and cleaner-disinfectants may be used without prior cleaning. Dilute product as directed. Application is by wet wipe, scrub, flood, flush, rinse, or spray methods. Observe required contact time. Rinse where required. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears. The use of sanitizing solutions other than those identified in Title 21 Code of Federal Regulations, Section 178.1010; disinfecting solutions; one-step cleaner-sanitizers or one-step cleaner-disinfectants must always be followed by a potable water rinse when applied to any food contact surfaces.

	Site, Efficacy, Dosage and Formulation	Use Directions

Sickroom Premises and Contents (continued)

A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2 virus	
A29	Fungicide	
FYABQBB	Mold/mildew	
	14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
	2,000 ppm 2,500-5,000 ppm quat 445,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
	2,000 ppm 2,500-5,000 ppm quat 412,000-628,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
	3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.

(Commercial and Industrial Uses)

/770020A-1	Athletic and Recreational Equipment	General Instructions for Use: The product registered in this site is for use on athletic and recreational equipment surfaces. Product label may recommend precleaning of surface prior to treatment. Apply product by spray, cloth, mop, sponge, brush, or pump spray. Thoroughly wet surfaces and allow for required contact period.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Athletic and Recreational Equipment (continued)	
A18 A22 A24	Pseudomonacide Disinfectant Deodorizer	
	14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
/770000A	Commercial, Industrial and Institutional Premises and Equipment (Non-Medical)	General Instructions for Use: The products registered in this site are for use on commercial, industrial, institutional, and public premises and equipment. This site includes the premises and equipment of the following areas: 1) Commercial - hotels, motels, theaters, office buildings, airports, bus stations, and train terminals. 2) Industrial - factories, mills, industrial plants and areas. 3) Institutional - schools, colleges, camps, corridors, offices, auditoriums, institutions, and asylums. 4) Public areas - public areas, public buildings, or public rooms. Premises is defined to include: ceilings, doors, doorknobs, fixtures, floors, light switches, stairs, walls, windows, and woodwork. Remove heavy surface soil or preclean surfaces prior to treatment as indicated by label instructions. One step cleaner-sanitizers and cleaner-disinfectants may be used without prior cleaning of lightly or moderately soiled surfaces. Dilute product according to label directions. Apply product by mop, scrub, sponge, spray, or automatic machine process. Wet surfaces thoroughly. Allow recommended contact time. Drain surface or rinse with potable water where required. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry.

Site, Efficacy, Dosage and Formulation	Use Directions
Commercial, Industrial and Institutional Premises and Equipment (Non-Medical) (continued)	
	Do not rinse. Repeat periodically or when mold/mildew growth appears.
A24 Bacteriostat	
348 ppm 521 ppm (3% SC/L)	Bacteriostatic treatment for surfaces. Formulated with lauryl diethanolamide and N-lauryl diethylenetriamine.
500 ppm (0.05% RTU)	Bacteriostatic treatment for surfaces.
A18 Pseudomonacide	
A19 Tuberculocide	
A22 Disinfectant	
A24 Deodorizer	
A25 Virucide-effective against Influenza Type A2 virus	
A29 Fungicide	
FYABQBB Mold/mildew	
3-9 ppm 905-2,630 ppm (0.02% SC/L)	Disinfection and cleaning of surfaces. Formulated with o-benzyl-p-chlorophenol; p-tert-amylphenol; and o-phenylphenol, sodium salt.
26-59 ppm 400-882 ppm quat 27-59 ppm (0.1% SC/L)	Disinfection of surfaces. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and N-alkyl*-N-ethyl morpholinium ethyl sulfate *alkyl (92% C18, 8% C16).
155-458 ppm 2,210-6,540 ppm (2% SC/L)	Disinfection and cleaning of surfaces. Formulated with o-benzyl-p-chlorophenol, p-tert-amylphenol, o-phenylphenol, propylene glycol, potassium hydroxide, and potassium ricinoleate.
14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Commercial, Industrial and Institutional Premises and Equipment (Non-Medical) (continued)	
	134 ppm 1,000 ppm quat 450,000 ppm (0.0134% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14), and triethylene glycol.
	3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.
	7,000 ppm 553,000 ppm (0.7% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and N-lauryl diethylenetriamine.
/700000A	Commercial Transportation Vehicles	General Instructions for Use: The products registered in this site are for use on commercial transportation vehicle surfaces. This includes buses, railroad cars, steamships, automobiles, airplanes, boats, and other conveyances. Preclean surfaces of vehicle or conveyance. Dilute product as recommended on label. Apply solution by mop, swab, rag, cloth, or spray. Allow required contact time. Rinse treated surfaces or allow to air dry in accordance with label instructions. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A18	Pseudomonacide	
A22	Disinfectant	
A24	Deodorizer	
A29	Fungicide	
FYABQBB	Mold/mildew	
	26-59 ppm 400-882 ppm quat 27-59 ppm (0.1% SC/L)	Disinfection of surfaces. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and N-alkyl*-N-ethyl morpholinium ethyl sulfate *alkyl (92% C18, 8% C16).

Site, Efficacy, Dosage and Formulation	Use Directions

Commercial Transportation Vehicles (continued)

500 ppm 1,500 ppm (0.05% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol.

(Food and Feed Processing Plants)

General Information:
Equipment and food contact surfaces general instructions for use: Thoroughly clean and rinse equipment. Sanitize immediately before equipment is to be used, or as specified by local regulations. One-step sanitizer-cleaners and disinfectant-cleaners may be used without prior cleaning. Dilute product as directed. Application may be by wet wipe, scrub, flood, flush, rinse, circulation, immersion, or spray methods.

Observe local regulations regarding contact period of the sanitizing solution. A 2 minute contact time is stipulated by health departments that follow the United States Public Health Service Ordinance and Code. Adhere to manufacturer's instructions regarding the temperature of diluent and rinse. Drain equipment and food contact surfaces thoroughly. Rinse with potable water when required.

Sanitizing solutions are regulated by the Food and Drug Administration as Indirect Food Additives under Title 21, Code of Federal Regulations, Section 178.1010. Solutions specified in this section may be safely used on food processing equipment within the prescribed conditions. The solutions may not exceed specified concentrations. A potable water rinse is not required following the use of the solutions, provided the equipment and surfaces are adequately drained before contact with food. The solutions may not exceed specified concentrations. A potable water rinse is required when drainage alone is inadequate to prevent adulteration of food products.

The use of sanitizing solutions other than those identified in Title 21 code of Federal Regulations, Section 178.1010, disinfecting solutions, one-step sanitizer-cleaners and disinfectant-cleaners must always be followed by a potable water rinse.

Premises (i.e. floors, walls, and other non-food contact surfaces) general instructions for use: Product directions may require a precleaning step before treatment. Remove all particulate contamination. Application may be by wipe, scrub, rinse, mop, or spray. Allow recommended contact time. Remove or carefully protect food products and food packaging materials before using quaternary ammonium products. Avoid contamination of food contact surfaces and food when applying pesticide solutions. Drain surfaces thoroughly. Rinse with potable water where required.

For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow

	Site, Efficacy, Dosage and Formulation	Use Directions
	General Information (continued)	
	to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.	
/71000JE	Food Processing Equipment and Surfaces	General Instructions for Use: The product registered in this site is for use on food processing equipment (i.e. blanchers, evaporators, fillers, tanks, vats, pipelines, valves, utensils, cutting boards, and other food contact surfaces).
A22	Disinfectant	
A24	Deodorizer	
A29	Fungicide	
	26-59 ppm 400-882 ppm quat 27-59 ppm (0.1% SC/L)	Disinfection of surfaces. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and N-alkyl*-N-ethyl morpholinium ethyl sulfate *alkyl (92% C18, 8% C16).
/71000JF	Food Processing Plant Premises	General Instructions for Use: The products registered in this site are for use on food processing plant premises (i.e. floors, walls, and other non-food contact surfaces).
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2 virus	
A29	Fungicide	
FYABQBB	Mold/mildew	
	26-59 ppm 400-882 ppm quat 27-59 ppm (0.1% SC/L)	Disinfection of surfaces. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and N-alkyl*-N-ethyl morpholinium ethyl sulfate *alkyl (92% C18, 8% C16).
	3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.

Site, Efficacy, Dosage and Formulation	Use Directions
(Eating Establishments)	
/72006JE Eating Establishment Equipment and Utensils	General Instructions for Use: The products registered in this site are for use on equipment and utensils in eating establishments (i.e. restaurants, taverns, bars, cafeterias, etc.) where food and beverages are served. Utensils include silverware, dishes, glassware, and similiar cooking and eating utensils. Equipment includes fixtures, stoves, sinks, and refrigerators. For the treatment of utensils: 1) Remove surface soils by scraping or flushing with water. 2) Wash with a suitable detergent or cleaner. 3) Rinse with clean water. 4) Sanitize in solution of product. Immerse all utensils in sanitizing solution for at least 2 minutes, or for contact period specified by governing sanitary code. 5) Rinse with potable water if required. 6) Drain and allow to air dry. Do not use a towel to dry. For the treatment of equipment: 1) Clean all equipment prior to treatment with product. One-step cleaner-sanitizers and cleaner-disinfectants do not require a precleaning step. 2) Dilute products according to label directions. 3) Apply by mop, sponge, wipe, or spray. 4) Products may require a rinse with potable water prior to equipment reuse. 5) Products may recommend treated surfaces be allowed to air dry. One-step cleaner-sanitizers and cleaner-disinfectants may be used without prior cleaning. Observe local regulations regarding contact period of the sanitizing solution. A minimum of 2 minutes contact time is stipulated by health departments that follow the United States Public Health Service Ordinance and Code. Adhere to manufacturer's instructions regarding the temperature of diluent and rinse. Drain equipment and food contact surfaces thoroughly. Rinse with potable water when required.

Site, Efficacy, Dosage and Formulation	Use Directions

Eating Establishment Equipment and Utensils (continued)

Sanitizing solutions are regulated by the Food and Drug Administration as Indirect Food Additives under Title 21, Code of Federal Regulations, Section 178.1010. Solutions specified in this section may be safely used on food processing equipment within the prescribed conditions. The solutions may not exceed specified concentrations. A potable water rinse is required when drainage alone is inadequate to prevent adulteration of food products.

The use of sanitizing solutions other than those identified in Title 21, Code of Federal Regulations, Section 178.1010; disinfecting solutions; one-step cleaner-sanitizers and cleaner-disinfectants must always be followed by a potable water rinse.

For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.

A18 Pseudomonacide
A19 Tuberculocide
A22 Disinfectant
A24 Deodorizer
A25 Virucide-effective against Influenza Type A2 virus
A29 Fungicide
FYABQBB Mold/mildew

200 ppm 3,800 ppm (0.02% PrL)	Disinfection and mold/mildew control on surfaces Formulated with o-phenylphenol, 4-chloro-2-cyclopentylphenol, and lauryl diethanolamide.
2,000 ppm 2,500-5,000 ppm quat 445,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
2,000 ppm 2,500-5,000 ppm quat 412,000-555,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.

	Site, Efficacy, Dosage and Formulation	Use Directions
/72000JF	Eating Establishment Premises	
		General Instructions for Use: The products registered in this site are for use on eating establishment premises (i.e. floors, walls, and other non-food contact surfaces). Eating establishment premises include commercial restaurants and cafeterias, institutional and household kitchens and dining areas, etc. Preclean surfaces before treatment with the antimicrobial solution. One-step cleaner-sanitizers and cleaner-disinfectants do not require a precleaning step. Dilute product according to label directions. Apply by mop, spray, cloth, sprinkle, scrub, brush, or machine apparatus. Thoroughly wet surfaces to be treated. Avoid contamination of foods or food contact surfaces. Some products require a rinse with potable water following the antimicrobial treatment. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A24	Bacteriostat	
	348 ppm 521 ppm (3% SC/L)	Bacteriostatic treatment for surfaces. Formulated with lauryl diethanolamide and N-lauryl diethylenetriamine.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2 virus	
A29	Fungicide	
FYABQBB	Mold/mildew	
	3-9 ppm 905-2,630 ppm (0.02% SC/L)	Disinfection and cleaning of surfaces. Formulated with o-benzyl-p-chlorophenol; p-tert-amylphenol, and o-phenylphenol, sodium salt.
	26-59 ppm 400-882 ppm quat 27-59 ppm (0.1% SC/L)	Disinfection of surfaces. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and N-alkyl*-N-ethyl morpholinium ethyl sulfate *alkyl (92% C18, 8% C16).

Site, Efficacy, Dosage and Formulation	Use Directions
Eating Establishment Premises (continued)	
155-458 ppm	Disinfection and cleaning of surfaces.
2,210-6,540 ppm (2% SC/L)	Formulated with o-benzyl-p-chlorophenol, p-tert-amylphenol, o-phenylphenol, propylene glycol, potassium hydroxide, and potassium ricinoleate.
14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
2,000 ppm 5,000 ppm quat 629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
2,000 ppm 2,500-5,000 ppm quat 412,000-628,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
(Food Markets)	
/730020A **Food Market Premises**	General Instructions for Use: The product registered in this site is for use on food market or food store premises (i.e. walls, floors, and other non-food contact surfaces). A precleaning step before treatment is recommended if surfaces are heavily soiled. Dilute product as recommended. Application is by mop, spray, sponge, or machine. Do not permit product to come in contact with food. If food contact surfaces are contacted by product solution, rinse surfaces with potable water prior to reuse. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Food Market Premises (continued)	
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2 virus	
FYABQBB	Mold/mildew	
	3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.
	(Hospital and Related Institutions)	
/74012GA-2	Hospital Critical Equipment	General Instructions for Use: The product registered in this site is for use on hospital equipment that requires more stringent antimicrobial treatment than general hospital equipment. This includes equipment which contacts the blood, tissue, or mucous membranes of the patient or equipment which is used in operating rooms, isolation wards, nurseries, and other critical hospital areas. Lensed instruments and fiberoptics, anesthesia and respiratory therapy equipment, and hemodialysis machines are in this site. Disassemble items as much as possible. Remove all visible soil before treatment with a disinfectant. Before treatment with a one-step disinfectant-cleaner remove heavy soil; during treatment remove other visible soil. For an antimicrobial to be effective all surfaces of the item must come in contact with the chemical for the required contact time. All surfaces must be rinsed with water when recommended. In the case of narrow tubing or catheters this may require flushing with a needle and syringe. Site Specific General Warnings: If possible, critical equipment should be sterilized with heat or ethylene oxide. Phenolics and quaternary ammonium compound solutions do not destroy bacterial spores, hepatitis or hydrophilic viruses. Quaternary ammonium compounds also do not destroy Mycobacterium tuberculosis.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Hospital Critical Equipment (continued)	
		For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
FYABQBB	Mold/mildew	
	476 ppm 769 ppm (3.1% SC/L)	Disinfection and mold/mildew control on surfaces. Formulated with o-benzyl-p-chlorophenol, potassium salt.
/740000A	Hospital Premises and Equipment	
		General Instructions for Use: The products registered in this site are for use in hospitals and medical facility premises (i.e. floors, walls, ceilings, fixtures, air ducts, and environmental surfaces) and on hospital non-critical contents (i.e. furniture, bedframes, telephones, tables, carts, physical therapy equipment, bedpans, basins, and janitorial equipment). Some products are intended for use on hospital conductive floors. Medical facilities include nursing homes, doctor and dentist offices, laboratories, and sanitariums. Hospital noncritical contents includes those items, hard surfaces, equipment, and furniture that do not contact the patient or only contact the patient's skin. Surfaces must be precleaned with detergent and rinsed with water before treatment with a disinfectant solution. One-step disinfectant-cleaners will clean and disinfect in 1 step in the presence of light to moderate soil conditions, heavy surface soil must be removed before treatment. Dilute products according to label directions and apply. Methods of Application: Flood application. Cover surface with solution. Allow required contact time. An automatic scrubber may be used to loosen soil. Remove solution with wet vacuum pick-up.

Site, Efficacy, Dosage and Formulation	Use Directions
Hospital Premises and Equipment (continued)	
	Mop, sponge, or cloth application. Dip applicator in pail of solution and apply to surface. A double bucket method is preferred for one-step cleaning and disinfecting. The applicator is dipped in a rinse bucket of the solution to flush out soil before being returned to wash bucket. Spray application. Product is 1) in pressurized spray container or 2) solution is to be applied by hand-trigger spray dispenser. Spray with product from a distance of 6 to 8 inches until surface is moist. For one-step cleaning-disinfecting, wipe surface clean with sponge or cloth. Fog application. Close all doors and windows and remove humans and animals from room. Apply product with electric sprayer or mechanical fogging equipment. Refer to product directions for rate, duration, and frequency of spraying, and required interval before re-entering room. Fogging is an adjunct to standard cleaning and disinfecting. Following fogging, clean and disinfect surfaces manually. After cleaning or rinsing hospital floors, soil containing solutions must be removed (i.e. by wet vacuum pick-up). Following disinfectant treatment, a rinse with water is usually not required. Dried residue of disinfectant on conductive flooring (i.e. in operating rooms) must not interfere with floor conductivity if a flammable anesthetic will be used in the room. Products which meet this requirement are in accordance with the National Fire Protection Association (N.F.P.A) Standard 56A and are registered for use on conductive flooring. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A24 Bacteriostat	
500 ppm (0.05% RTU)	Bacteriostatic treatment for surfaces.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Hospital Premises and Equipment (continued)	
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2, Herpes simplex and Vaccinia viruses	
A29	Fungicide	
FYABQBB	Mold/mildew	
	3-9 ppm 905-2,630 ppm (0.02% SC/L)	Disinfection and cleaning of surfaces. Formulated with o-benzyl-p-chlorophenol; p-tert-amylphenol; and o-phenylphenol, sodium salt.
	26-59 ppm 400-882 ppm quat 27-59 ppm (0.1% SC/L)	Disinfection of surfaces. Formulated with alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and N-alkyl*-N-ethyl morpholinium ethyl sulfate *alkyl (92% C18, 8% C16).
	155-458 ppm 2,210-6,540 ppm (2% SC/L)	Disinfection and cleaning of surfaces. Formulated with o-benzyl-p-chlorophenol, p-tert-amylphenol, o-phenylphenol, propylene glycol, potassium hydroxide, and potassium ricinoleate.
	476 ppm 769 ppm (3.1% SC/L)	Disinfection and mold/mildew control on surfaces. Formulated with o-benzyl-p-chlorophenol, potassium salt.
	14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
	134 ppm 1,000 ppm quat 450,000 ppm (0.0134% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14), and triethylene glycol.
	240 ppm 786,000 ppm (0.024% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and o-phenylphenol.

Site, Efficacy, Dosage and Formulation	Use Directions

Hospital Premises and Equipment (continued)

2,000 ppm 5,000 ppm quat 629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
2,000 ppm 2,500-5,000 ppm quat 412,000-628,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.
10,000 ppm 280,000 ppm (1% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with isopropanol.

/74011GA-2 Surgical Instruments

General Instructions for Use: The product registered in this site is for use on surgical instruments and hospital, medical, and/or laboratory critical instruments. Critical instruments are those instruments which penetrate the tissue or make intimate contact with the blood or the mucous membranes of the body.

Instrument surfaces must be precleaned with soap or detergent and rinsed with water before treatment with an antimicrobial solution. Instruments should be scrubbed free of organic debris and allowed to drain dry. One-step disinfectant-cleaners will clean and disinfect in one step only in the presence of light to moderate soil conditions; heavy surface soil must be removed before treatment with a one-step disinfectant-cleaner.

Methods of Application:

Instrument presoak. Lightly to moderately soiled instruments are immersed in disinfectant-cleaner solution immediately after use and before cleaning and terminal disinfection.

Wipe treatment. Instrument surfaces are sprayed until wet.

Site, Efficacy, Dosage and Formulation	Use Directions
Surgical Instruments (continued)	
	Solution immersion. Product is a ready-to-use solution or a concentrate which is diluted with water according to label instructions. The instruments are immersed in the solution; if the product is a disinfectant-cleaner, the instruments must be rubbed or brushed free of soil. To disinfect or sterilize all surfaces, the instrument must make contact with the solution, being careful to avoid entrapment of air bubbles. Required contact time and rinse directions must be observed. If no contact time is given, allow a minimum of 10 minutes. Sodium nitrite should be added to inhibit rust when recommended.
	Site Specific General Warnings: If possible, critical instruments should be sterilized with heat or ethylene oxide. Phenolics and quaternary ammonium compound solutions do not destroy bacterial spores, hepatitis or hydrophilic viruses. Quaternary ammonium compounds also do not destroy Mycobacterium tuberculosis.
	For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A19 Tuberculocide A22 Disinfectant A24 Deodorizer FYABQBB Mold/mildew	
476 ppm 769 ppm (3.1% SC/L)	Disinfection and mold/mildew control on instruments. Formulated with o-benzyl-p-chlorophenol, potassium salt.

	Site, Efficacy, Dosage and Formulation	Use Directions
	(Industrial Preservatives and Additives)	
/810120A	Latex and Resin Emulsions	General Instructions for Use: The products registered in this site are used to control the growth of bacteria and fungi in latex and resin emulsions during manufacture and storage. These chemical products are for industrial use only. Add product to the latex or resin emulsion at a point during the manufacturing process where there is sufficient time and agitation for good dispersion.
A24	Bacteriostat	
	158 ppm 40 ppm (79% SC/S)	Bacteriostatic treatment for PVA latex emulsions. Add 0.02 percent of product based on the weight of the emulsion. Formulated with zinc 2-pyridinethiol 1-oxide.
	1,980 ppm (99% SC/S)	Bacteriostatic treatment for resin emulsions. Add 0.2 percent of product based on the weight of the resin.
/810050A	Leather and Leather Products	General Instructions for Use: The product registered in this site is for use on leather and leather products. It is used to control the growth of protein digesting bacteria (during short term transit from soaking plant to tannery or curing plant) on rawhide. This product is for industrial use only, and is to be added to various steps in leather processing according to the following methods of application: Fresh-hide spray method. Spray product on the hair side of washed and fleshed hides. Trimmings for animal feed should be removed from the hides prior to application. Fresh treated hides should not be exposed for more than 3 days before further processing. Soak method. Add product to the solutions used in paddle, drum, and vat soaking. Use as a precaution against bacterial action. Agitate 20 to 30 minutes.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Leather and Leather Products (continued)	
A24	Bacteriostat	
	250-2,500 ppm 1,950-19,500 ppm (10% RTU)	Bacteriostatic treatment for leather. Add 0.25 percent to 2.5 percent of product based on the weight of the leather. Formulated with isopropanol.
/810090A	Paints	
		General Instructions for Use: The product registered in this site is a bacteriostat and fungistat used to control bacteria and fungi in paints during manufacture and in-can storage. This product is a preservative for in-can storage and is not considered to be effective in protecting dried paint films from bacterial or fungal attack. This product is for industrial use only. It is added at a point in the paint manufacturing process where there is sufficient time and agitation for good dispersion. Product is added as a liquid, dry solid, or concentrated aqueous solution. Product directions may specify addition at a specific phase in the manufacturing process or to the raw materials. Some products are used as a mixture with other antimicrobial products. The exact product concentration required will vary with the type of system to be treated, the nature and extent of microbiological contamination, the degree of control required, temperature, and pH. The exact amount of product required is best determined by actual test.
A24	Bacteriostat	
	158 ppm 40 ppm (79% SC/S)	Bacteriostatic treatment for exterior latex paints (acrylic, PVA, water base latex paint). Add 0.02 percent of product based on the weight of the paint. Formulated with zinc 2-pyridinethiol 1-oxide.
FYABQBB	Mold/mildew	
	1,980 ppm 500 ppm (79% SC/S)	Mold/mildew control for exterior latex paints (acrylic, PVA, water base latex paint). Add 0.25 percent of product based on the weight of the paint. Formulated with zinc 2-pyridinethiol 1-oxide.

	Site, Efficacy, Dosage and Formulation	Use Directions
/810100A	Paper and Paper Products	General Instructions for Use: The products registered in this site are used to control the growth of bacteria and fungi on paper and paper products. Apply products according to the following methods of application. Beater application: Add product to the pulp at the beaters. The degree of retention of the active ingredient(s) will depend on the nature of other additives in the system. Spray application: Spray paper uniformly with the product. Use conventional spray equipment. Conduct application in a spray booth or well ventilated area. Impregnation application: Apply product to the dry end of the paper machine or as an off-the-machine operation. Apply by size press, rollcoater, calendar, or pad bath.
A24	Bacteriostat	
	250-2,500 ppm 1,950-19,500 ppm (10% RTU)	Bacteriostatic treatment for paper. Add 0.25 percent to 2.5 percent of product based on the weight of the paper. Formulated with isopropanol.
/810110A	Plastics and Polymers	General Instructions for Use: The products registered in this site are bacteriostats and fungistats for use in plastic, plastic products and synthetic polymers. The majority of products included in this section are incorporated as antimicrobial additives of plastics, plastic films, vinyl, and other synthetic polymers during the manufacturing process. These products are intended to control the growth of bacteria and fungi during the service life of the plastic or polymer. Other products included in this section are intended for the treatment of plastic surfaces or are impregnated plasticized vinyl products which claim residual bacteriostatic activity. Mixing or Milling application: Incorporate product into the plastic mix. Mix thoroughly to ensure even dispersion.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Plastics and Polymers (continued)	
		Spray application: Apply by conventional spray equipment. Spray plastic uniformly with the product. Conduct application in a spray booth or well ventilated area.
A24 FYABQBB	Bacteriostat Mold/mildew	
	2,000 ppm 3,700 ppm (0.2% Impr)	Product is a bacteriostatic disposable plastic garbage bag. Formulated with dimethyl phthalate and 5-chloro-2-(2,4-dichlorophenoxy)phenol.
	3,160 ppm 800 ppm (79% SC/S)	Bacteriostatic treatment and mold/mildew control for PVC plastic (non-food use). Add 0.4 percent of product based on the weight of the plastic. Formulated with zinc 2-pyridinethiol 1-oxide.
	19,400 ppm 400 ppm (99% SC/S)	Bacteriostatic treatment for plastic. Add 0.4 percent of product based on the weight of the resin.
/810140A	Specialty Products	
		General Instructions for Use: The product registered in this site is for use in miscellaneous products not included in other Industrial Preservative sites. This includes solutions and emulsions of unspecified use, joint cements, protein colloids, inks, dyes, ceramic glazes, waxes, polishes, cleansers, liquid detergents, photographic solutions, fire extinguisher solutions, milk samples (Babcock), and air filter material. Add product during the manufacturing process and mix thoroughly to ensure uniform distribution.
A24	Bacteriostat	
	99 ppm 25 ppm (79% SC/S)	Bacteriostatic treatment for dry wall joint cement. Add 0.0125 percent of product based on the weight of the cement. Formulated with zinc 2-pyridinethiol 1-oxide.

	Site, Efficacy, Dosage and Formulation	Use Directions
/810150A	Textiles	General Instructions for Use: The products registered in this site are bacteriostats and fungistats for use on textile fabrics during the manufacturing process. Many products are incorporated into the textile fabric for residual bacteriostatic and fungistatic activity. The products are for industrial use only. Padding operations: When product is incorporated into the fabric during padding operations, it is necessary to know the liquid pick-up value of the textile material in order to determine the necessary use concentration of the product. If the liquid pick-up is 50 percent, to deposit 0.5 percent of product requires a 1 percent product concentration in the treatment bath. The percentage of product deposited is calculated based on the dry weight of the textile fabric. Product may be applied by immersion, spray, padders, or in a dyebeck, jig, paddle machine, or rotary wheel. Spray applications: Use conventional spray equipment. Spray textile material as uniformly as possible. Apply spray in a booth or well ventilated area.
A24	Bacteriostat	
	280 ppm 140 ppm (5% RTU)	Bacteriostatic treatment for fabrics. Use 43 fluid ounces of product per 100 pounds of fabric. Formulated with N-lauryl diethylenetriamine.
	501-2,500 ppm 390-19,500 ppm (10% RTU)	Bacteriostatic treatment for textiles. Add 0.05 percent to 0.75 percent of product based on the dry weight of the textiles. Formulated with isopropanol.
	750-1,500 ppm 500-1,000 ppm (15% RTU)	Bacteriostatic treatment for textiles. Add 0.5 percent to 1 percent of product based on the weight of the textiles. Formulated with 2,2'-methylenebis(3,4,6-trichlorophenol).
FYABQBB	Mold/mildew	
	16 ppm 16 ppm (6.2% SC/L)	Mold/mildew control for fabrics. Add 2 fluid ounces of product per 100 pounds of fabric. Formulated with salicylanilide.

	Site, Efficacy, Dosage and Formulation	Use Directions
	(Domestic and Human Uses)	
/860050A	Human Footwear	General Instructions for Use: The products registered in this site are for use on the inner surfaces of street shoes, athletic shoes (bowling, golf, tennis, etc.), skates, rental shoes, and other footwear. May also be used on the exterior surfaces of protective boots and shoes worn by workers, farmers, hospital personnel, and veterinarians to decontaminate footwear and to aid in reducing the spread of infectious organisms from 1 building or area to another. Methods of Application.: Spray: Spray surface until wet. Air dry. Immersion: Dilute concentrate with water to obtain required dilution. Immerse footwear in solution. Observe required contact time. Rinse with water if required. Air dry. Wipe: Dilute concentrate with water to obtain required dilution. Wash surface with sponge, cloth, or brusn dipped in solution. Rinse with water if required. Air dry.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A29	Fungicide	
FYABQBB	Mold/mildew	
	450 ppm 1,500 ppm (0.045% PrL)	Disinfection and mold/mildew control for shoes. Formulated with o-phenylphenol and 4-chloro-2-cyclopentylphenol.
	7,000 ppm 553,000 ppm (0.7% PrL)	Disinfection and mold/mildew control for shoes. Formulated with ethyl alcohol, o-phenylphenol, and N-lauryl diethylenetriamine.

	Site, Efficacy, Dosage and Formulation	Use Directions
	(Bathrooms)	
/880030A	Bathroom Premises	
		General Instructions for Use: The products registered in this site are for use in bathroom premises (i.e. floors, walls, sinks, bathtubs, shower stalls, toilet seats, toilet exterior surfaces, and fixtures). Included are products for hospital, institutional, commercial, industrial, and household use. Preclean surfaces prior to treatment. A precleaning step is not required for one-step disinfectant-cleaners. Dilute product as directed. Apply by mop, sponge, brush, cloth, or spray. Wet surfaces thoroughly. Allow required contact time. Rinse where required. Porous surfaces such as grout and unfinished or scarred surfaces may require a higher concentration of solution than non-porous surfaces such as porcelain and tile. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A24	Bacteriostat	
	348 ppm 521 ppm (3% SC/L)	Bacteriostatic treatment for surfaces. Formulated with lauryl diethanolamide and N-lauryl diethylenetriamine.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2, Herpes simplex and Vaccinia viruses	
A29	Fungicide	
FYABQBB	Mold/mildew	
	2,000 ppm (0.2% RTU)	Disinfection and mold/mildew control on surfaces.

Site, Efficacy, Dosage and Formulation	Use Directions
Bathroom Premises (continued)	
14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
134 ppm 1,000 ppm quat 450,000 ppm (0.0134% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14), and triethylene glycol.
200 ppm 3,800 ppm (0.02% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol, 4-chloro-2-cyclopentylphenol, and lauryl diethanolamide.
240 ppm 786,000 ppm (0.024% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and o-phenylphenol.
500 ppm 1,500 ppm (0.05% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol.
2,000 ppm 9,400 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with polyvinylpyrrolidone.
2,000 ppm 2,500-5,000 ppm quat 437,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
2,000 ppm 2,500-5,000 ppm quat 412,000-628,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.
7,000 ppm 553,000 ppm (0.7% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and N-lauryl diethylenetriamine.

	Site, Efficacy, Dosage and Formulation	Use Directions
/880090A	Diaper Pails	General Instructions for Use: The products registered in this site are for use on diaper pail surfaces against pathogenic and/or odor-causing bacteria. Preclean diaper pail with soap or detergent and rinse before disinfectant treatment. For one-step disinfectant-cleaners, remove heavy organic soil prior to treatment. Dilute product with water as directed. Observe required contact time. Pressurized liquid formulations are to be sprayed from a distance of 6 to 12 inches. Spray surface until thoroughly wet. Allow surface to dry. For one-step disinfectant-cleaners, wipe surface clean with a sponge or cloth after application. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2 virus	
A29	Fungicide	
FYABQBB	Mold/mildew	
	134 ppm 1,000 ppm quat 450,000 ppm (0.0134% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14), and triethylene glycol.
	2,000 ppm 2,500-5,000 ppm 438,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
	2,000 ppm 2,500-5,000 ppm 412,000-628,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.

	Site, Efficacy, Dosage and Formulation	Use Directions
/880040A	Toilet Bowls and Urinals	
		General Instructions for Use: The products registered in this site are for use on toilet bowl and urinal surfaces and water. Pressurized liquid formulations are to be sprayed from a distance of 6 to 12 inches. Spray surface until thoroughly wet. Allow surface to dry. For one-step disinfectant-cleaners, wipe surface clean with a sponge or cloth after application. For mold/mildew control, preclean hard non-porous surfaces prior to treatment when required. Apply by sponge, cloth, mop, or spray. Allow to dry. Do not rinse. Repeat periodically or when mold/mildew growth appears.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2, Herpes simplex and Vaccinia viruses	
A29	Fungicide	
FYABQBB	Mold/mildew	
	200 ppm 3,800 ppm (0.02% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol, 4-chloro-2-cyclopentylphenol, and lauryl diethanolamide.
	240 ppm 786,000 ppm (0.024% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and o-phenylphenol.
	2,000 ppm 2,500-5,000 ppm quat 445,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
	2,000 ppm 2,500-5,000 ppm quat 412,000-628,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
	3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.

	Site, Efficacy, Dosage and Formulation	Use Directions
	(Laundry)	
/87007HE	Diapers (Household)	General Instructions for Use: The product registered in this site is for use on small loads of diapers. The products provide instructions for hand washing, use in small automatic machines, or dosages based on 10 pounds of dry fabric. Products in this section are for household use or for general use. The object of control of the residual bacteriostats is to inhibit the growth of odor-causing and ammonia-producing bacteria (i.e. Brevibacterium ammoniagenes.) which act on urine in diapers. Residual antimicrobial activity is effective only under conditions of high relative humidity or wet contamination. For Use: Do not pour product directly on diapers. Add product to water before immersing diapers. Methods of Application: 1) Wash Water Additive: a) Hand washing. Add product to wash water and add detergent if directed. Immerse diapers and allow them to remain in water for a minimum of 5 minutes while washing. b) Automatic machine. Add product to wash water. 2) First rinse additive: a) Hand washing. Squeeze suds from diapers. Prepare a dilute solution of product and soak diapers in solution for a minimum of 5 minutes. Rinse all trace of product from diaper with final rinse. b) Automatic machine. No applications. 3) Final rinse additive: a) Hand washing. Rinse all soap from diapers. Immerse diapers in dilute solution of product for 5 minutes. b) Automatic machine. Add product to final rinse cycle.
A24	Bacteriostat 8 ppm (0.15% SC/S)	Bacteriostatic treatment for diapers.

	Site, Efficacy, Dosage and Formulation	Use Directions
/87007HE	Diapers (Presoak)	General Instructions for Use: The product registered in this site is for the treatment of soiled diapers prior to laundering. The treatment is intended to destroy or inhibit the growth of odor-causing bacteria. Methods of Application: Presoak-Diaper Pail. Remove substantial soil by flushing diaper in toilet. Add product to clean water in diaper pail to prepare proper dilution or add ready-to-use product directly to pail. Soak soiled diapers in product solution until ready to launder. Washing Machine. Remove substantial soil by flushing diaper in toilet. Add product to water in washing machine to achieve proper dilution. Agitate diapers and soak for recommended contact time. Add soap or detergent and wash.
A24	Bacteriostat 44 ppm (0.15% SC/S)	Bacteriostatic treatment for diapers.
/87006HO	Laundry (Hospital, Commercial and Institutional)	General Instructions for Use: The products registered in this site are for use in the treatment of laundry (i.e. washable fabrics such as clothing, linens, sheets, towels, blankets, uniforms, and bathing suits) in commercial, institutional, and medical establishments (i.e., schools, resturants, hotels, motels, athletic facilities, and hospitals). Fabrics are treated in bulk or multifamily laundry loads. Commercial machines typically handle 50 to 100 pounds of fabric per load and have a lower fabric-to-water weight ratio (1:3 to 1:5) than home washing machines (1:10 to 1:15). Do not pour bleach, quaternary ammonium compounds or other soluble concentrates directly on fabrics. Add to wash wheel after machine has filled with water or dilute product in a gallon of water and add this solution to laundry.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Laundry (Hospital, Commercial and Institutional) (continued)	
		Methods of Application:
		Presoak. Prepare product dilution. Immerse contaminated fabric in solution. Allow for a minimum of 10 minutes contact time. Wash fabric after soaking.
		Prerinse additive. Spin fabric dry. Add product to wash wheel during prerinse cycle.
		Wash water additive. Add product to wash water with or without detergent as directed. Rinse fabric following treatment.
		First rinse additive. Wash fabric. Add product to first rinse water. Rinse fabric following treatment.
		Final rinse additive. Wash fabric and rinse free of all detergent. Add product to final rinse water or sour cycle.
A24	Bacteriostat	
	9-12 ppm (0.6% SC/S)	Bacteriostatic treatment for laundry.
	24-146 ppm (3.11% SC/L)	Bacteriostatic treatment for laundry.
/87006HE	Laundry (Household)	
		General Instructions for Use: The product registered in this site is for use in the treatment of household laundry (i.e. clothing, linens, sheets, towels, and dish cloths).
		Do not pour quaternary ammonium compound products directly on fabric. Add product after machine has been filled with water.
		Methods of Application:
		Presoak. Prepare product dilution. Immerse contaminated fabric in solution. Allow for a minimum of 10 minutes contact time. Wash fabric after soaking.
		Wash water additive (machine or handwash). Add product to wash water. Rinse fabric following treatment.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Laundry (Household) (continued)	
		First rinse additive. Wash fabric. Add product to first rinse water. Rinse fabric following treatment.
		Final rinse additive (machine or handwash). Wash fabric and rinse free of all detergent. Add product to final rinse water or sour cycle.
A24	Bacteriostat	
	4-8 ppm (0.15% SC/S)	Bacteriostatic treatment for laundry.
/870120A	Laundry (Mattresses, Pillows and Draperies)	
		General Instructions for Use: The products registered in this site are for use on mattresses, pillows, and draperies.
		Spray product onto fabric until surface is moist. Allow product to dry before use. Fabric is treated before use or between uses.
A18	Pseudomonacide	
A22	Disinfectant	
A24	Deodorizer	
FYABQBB	Mold/mildew	
	14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of mattresses, pillows, and draperies. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
	500 ppm 1,500 ppm (0.05% PrL)	Disinfection and mold/mildew control on mattresses, pillows, and draperies. Formulated with o-phenylphenol.

	Site, Efficacy, Dosage and Formulation	Use Directions
	(Refuse)	
/890010A	Garbage Containers	General Instructions for Use: The products registered in this site are for use on garbage container surfaces. Clean and rinse surfaces prior to treatment. One-step disinfectant-cleaners and sanitizer-cleaners do not require a precleaning step. Dilute product as directed on label. Application is by wipe, mop, swab, wash, rinse, or spray. Observe required contact time.
A18	Pseudomonacide	
A19	Tuberculocide	
A22	Disinfectant	
A24	Deodorizer	
A25	Virucide-effective against Influenza Type A2, Herpes simplex and Vaccinia viruses	
A29	Fungicide	
FYABQBB	Mold/mildew	
	14 ppm 3,400 ppm quat 421,000 ppm (0.0014% PrL)	Disinfection of surfaces. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.
	134 ppm 1,000 ppm quat 450,000 ppm (0.0134% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14), and triethylene glycol (083501).
	240 ppm 786,000 ppm (0.024% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and o-phenylphenol.
	500 ppm 1,500 ppm (0.05% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with o-phenylphenol.
	2,000 ppm 2,500-5,000 ppm quat 438,000-629,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).

	Site, Efficacy, Dosage and Formulation	Use Directions
	Garbage Containers (continued)	
	2,000 ppm 2,500-5,000 ppm quat 412,000-555,000 ppm (0.2% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
	3,600 ppm 550,000 ppm (0.36% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.
	7,000 ppm 553,000 ppm (0.7% PrL)	Disinfection and mold/mildew control on surfaces. Formulated with ethyl alcohol, o-phenylphenol, and N-lauryl diethylenetriamine.
	(Miscellaneous Indoor Uses)	
/900190A	Air Sanitizers	General Instructions for Use: The products registered in this site are for use as air sanitizers to reduce the number of airborne bacteria and viruses. These products may be for commercial (i.e. bathrooms, washrooms, auditoriums, public rooms, hotels, theaters, hospitals, factories, mills, schools, and department stores) and household use. Spray application. For products that are pressurized liquids marketed in pressurized spray containers, spray into air manually. For products registered for use in manufacturer's automatic dispensing devices, insert pressurized container in device. Preset device to depress valve of pressurized container at the desired evenly spaced intervals. Hang dispenser device above eye level in room to be treated. Do not install device in nurseries or rooms where infants, ill, or aged people are confined.
A23	Sanitizer	
	134 ppm 1,000 ppm quat 450,000 ppm (0.0134% PrL)	Sanitization of air. Formulated with ethyl alcohol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14), and triethylene glycol.
	240 ppm 786,000 ppm (0.024% PrL)	Sanitization of air. Formulated with ethyl alcohol and o-phenylphenol.

	Site, Efficacy, Dosage and Formulation	Use Directions
	Air Sanitizers (continued)	
	450 ppm 1,500 ppm (0.045% PrL)	Sanitization of air. Formulated with o-phenylphenol and 4-chloro-2-cyclopentylphenol.
	2,000 ppm 2,500-5,000 ppm 437,000-629,000 ppm (0.2% PrL)	Sanitization of air. Formulated with ethyl alcohol and alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16).
	2,000 ppm 5,000 ppm quat 518,000-628,000 ppm (0.2% PrL)	Sanitization of air. Formulated with ethyl alcohol and methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20%.
	3,600 ppm 550,000 ppm (0.36% PrL)	Sanitization of air. Formulated with ethyl alcohol, o-phenylphenol, and 4-chloro-2-cyclopentylphenol.
	10,000 ppm 280,000 ppm (1% PrL)	Sanitization of air. Formulated with isopropanol.
/900050A	Filters (Air Conditioning, Air and Furnace)	General Instructions for Use: The product registered in this site is a residual bacteriostat for air-conditioning, air, and furnace filters. Preclean filters by flushing with water. Use product in appropriate dilution. Apply product by sponge, spray, or immersion. Allow specified contact time.
A24	Bacteriostat	
	14 ppm 3,400 ppm 421,000 ppm (0.0014% PrL)	Bacteriostatic treatment for filters. Formulated with isopropanol, alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18), alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18), and bis(tributyltin)oxide.

Listing of Registered Pesticide Products by Formulation

&090.0002	90% formulation intermediate	
	4',5-dibromosalicylanilide (077402)	45.00%
	3,4',5-tribromosalicylanilide (077404)	45.00%
		90.00%
	001457-00043	
&099.0002	99% formulation intermediate	
	3,4',5-tribromosalicylanilide (077404)	97.00%
	3,5-dibromosalicylanilide (077405)	2.00%
		99.00%
	009571-00003	
&099.9902	100% formulation intermediate	
	4',5-dibromosalicylanilide (077402)	0.05%
	3,4',5-tribromosalicylanilide (077404)	99.95%
		100.00%
	001457-00047	
&000.2010	0.2% impregnated materials	
	3,4',5-tribromosalicylanilide (077404)	0.20%
	dimethyl phthalate (028002)	0.35%
	5-chloro-2-(2,4-dichlorophenoxy)phenol (054901)	0.02%
		0.57%
	007101-00003	
&000.1515	0.15% soluble concentrate/solid	
	3,4',5-tribromosalicylanilide (077404)	0.15%
	001624-00028	
&000.6015	0.6% soluble concentrate/solid	
	3,4',5-tribromosalicylanilide (077404)	0.6%
	006142-00016	
&079.0015	79% soluble concentrate/solid	
	4',5-dibromosalicylanilide (077402)	36.00%
	3,4',5-tribromosalicylanilide (077404)	36.00%
	3,5-dibromosalicylanilide (077405)	7.00%
	zinc 2-pyridinethiol 1-oxide (088002)	20.00%
		99.00%
	001258-00889	
&099.0015	99% soluble concentrate/solid	
	3,4',5-tribromosalicylanilide (077404)	99.00%
	003090-00098	
	3,4',5-tribromosalicylanilide (077404)	97.00%
	3,5-dibromosalicylanilide (077405)	2.00%
		99.00%
	006390-00029	

Listing of Registered Pesticide Products by Formulation (continued)

&200.0215 0.02% soluble concentrate/liquid

3,5-dibromosalicylanilide (077405)	0.02%
o-benzyl-p-chlorophenol (062201)	1.88%
p-tert-amylphenol (064101)	1.00%
o-phenylphenol, sodium salt (064104)	3.00%
	5.90%

005664-00039

&200.1015 0.1% soluble concentrate/liquid

3,4',5-tribromosalicylanilide (077404)	0.08%
3,5-dibromosalicylanilide (077405)	0.02%
alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18) (069104)	0.75%
alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18) (069111)	0.75%
N-alkyl*-N-ethyl morpholinium ethyl sulfate *alkyl (92% C18, 8% C16) (069113)	0.10%
	1.70%

000334-00246

&200.2515 0.25% soluble concentrate/liquid

4',5-dibromosalicylanilide (077402)	0.20%
3,4',5-tribromosalicylanilide (077404)	0.05%
	0.25%

000787-00035

&202.0015 2% soluble concentrate/liquid

4',5-dibromosalicylanilide (077402)	0.40%
3,4',5-tribromosalicylanilide (077404)	1.60%
o-benzyl-p-chlorophenol (062201)	3.75%
p-tert-amylphenol (064101)	2.00%
o-phenylphenol (064103)	6.00%
propylene glycol (068603)	6.00%
potassium hydroxide (075602)	1.80%
potassium ricinoleate (079023)	9.00%
	30.55%

005664-00037

&203.0015 3% soluble concentrate/liquid

4',5-dibromosalicylanilide (077402)	1.50%
3,4',5-tribromosalicylanilide (077404)	1.50%
lauryl diethanolamide (079018)	3.00%
N-lauryl diethylenetriamine (079055)	1.50%
	7.50%

001457-00051

&203.1015 3.1% soluble concentrate/liquid

4',5-dibromosalicylanilide (077402)	1.55%
3,4',5-tribromosalicylanilide (077404)	1.55%
o-benzyl-p-chlorophenol, potassium salt (062202)	5.00%
	8.10%

006018-00007

Listing of Registered Pesticide Products by Formulation (continued)

&203.1115 3.11% soluble concentrate/liquid

4',5-dibromosalicylanilide (077402)	1.56%
3,4',5-tribromosalicylanilide (077404)	1.55%
	3.11%

006018-00001

&206.2015 6.2% soluble concentrate/liquid

4',5-dibromosalicylanilide (077402)	2.80%
3,4',5-tribromosalicylanilide (077404)	3.40%
salicylanilide (077407)	6.20%
	12.40%

000335-00199

&200.0516 0.05% liquid-ready to use

3,4',5-tribromosalicylanilide (077404)	0.05%

000541-00099

4',5-dibromosalicylanilide (077402)	0.01%
3,4',5-tribromosalicylanilide (077404)	0.04%
	0.05%

000541-00103

4',5-dibromosalicylanilide (077402)	0.03%
3,4',5-tribromosalicylanilide (077404)	0.02%
	0.05%

000541-00171

&200.2016 0.2% liquid-ready to use

4',5-dibromosalicylanilide (077402)	0.04%
3,4',5-tribromosalicylanilide (077404)	0.16%
	0.20%

001624-00099

&205.0016 5% liquid-ready to use

4',5-dibromosalicylanilide (077402)	2.50%
3,4',5-tribromosalicylanilide (077404)	2.50%
N-lauryl diethylenetriamine (079055)	2.50%
	7.50%

001457-00048

&210.0016 10% liquid-ready to use

4',5-dibromosalicylanilide (077402)	0.09%
3,4',5-tribromosalicylanilide (077404)	9.60%
3,5-dibromosalicylanilide (077405)	0.31%
isopropanol (047501)	78.00%
	88.00%

003090-00152 003090-00153 003090-00154

&215.0016 15% liquid-ready to use

3,4',5-tribromosalicylanilide (077404)	15.00%
2,2'-methylenebis(3,4,6-trichlorophenol) (044901)	10.00%
	25.00%

003090-00194

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Listing of Registered Pesticide Products by Formulation (continued)

&299.9916	100% liquid-ready to use	
	4',5-dibromosalicylanilide (077402)	0.90%
	3,4',5-tribromosalicylanilide (077404)	96.00%
	3,5-dibromosalicylanilide (077405)	3.10%
		100.00%
	003090-00149	
&200.0019	0.0014% pressurized liquid	
	3,4',5-tribromosalicylanilide (077404)	0.0014%
	isopropanol (047501)	42.0000%
	alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18) (069104)	0.1700%
	alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (50% C12, 30% C14, 17% C16, 3% C18) (069111)	0.1700%
	bis(tributyltin)oxide (083001)	0.0500%
		42.3914%
	001769-00170	
&200.0119	0.0134% pressurized liquid	
	4',5-dibromosalicylanilide (077402)	0.0067%
	3,4',5-tribromosalicylanilide (077404)	0.0067%
	ethyl alcohol (001501)	37.0000%
	alkyl*dimethyl benzyl ammonium chloride *alkyl (60% C14, 30% C16, 5% C12, 5% C18) (069104)	0.0500%
	alkyl*dimethyl ethylbenzyl ammonium chloride *alkyl (68% C12, 32% C14) (069154)	0.0500%
	triethylene glycol (083501)	8.0000%
		45.1134%
	000257-00295 010744-00006	
&200.0219	0.02% pressurized liquid	
	4',5-dibromosalicylanilide (077402)	0.02%
	o-phenylphenol (064103)	0.10%
	4-chloro-2-cyclopentylphenol (064202)	0.08%
	lauryl diethanolamide (079013)	0.20%
		0.40%
	005590-00061	
&200.0319	0.025% pressurized liquid	
	3,4',5-tribromosalicylanilide (077404)	0.019%
	3,5-dibromosalicylanilide (077405)	0.005%
	ethyl alcohol (001501)	78.500%
	o-phenylphenol (064103)	0.136%
		78.650%
	000675-00025	
&200.0519	0.05% pressurized liquid	
	3,4',5-tribromosalicylanilide (077404)	0.05%
	o-phenylphenol (064103)	0.15%
		0.20%
	000706-00023	

Listing of Registered Pesticide Products by Formulation (continued)

&200.2019 0.2% pressurized liquid

3,4',5-tribromosalicylanilide (077404)	0.20%
polyvinylpyrrolidone (079033)	0.94%
	1.14%

005075-00020

4',5-dibromosalicylanilide (077402)	0.0400%
3,4',5-tribromosalicylanilide (077404)	0.1600%
ethyl alcohol (001501)	43.7425%
alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16) (069105)	0.2500%
	44.1925%

005590-00144

4',5-dibromosalicylanilide (077402)	0.04%
3,4',5-tribromosalicylanilide (077404)	0.16%
ethyl alcohol (001501)	44.53%
alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16) (069105)	0.25%
	44.98%

005590-00133

4',5-dibromosalicylanilide (077402)	0.04%
3,4',5-tribromosalicylanilide (077404)	0.16%
ethyl alcohol (001501)	62.90%
alkyl*dimethyl benzyl ammonium chloride *alkyl (50% C14, 40% C12, 10% C16) (069105)	0.50%
	63.60%

005590-00101

4',5-dibromosalicylanilide (077402)	0.040%
3,4',5-tribromosalicylanilide (077404)	0.160%
ethyl alcohol (001501)	41.246%
methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20% (069129)	0.250%
	41.696%

005590-00056

4',5-dibromosalicylanilide (077402)	0.040%
3,4',5-tribromosalicylanilide (077404)	0.160%
ethyl alcohol (001501)	51.775%
methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20% (069129)	0.500%
	52.475%

001266-00117

Listing of Registered Pesticide Products by Formulation (continued)

0.2% pressurized liquid (continued)

4',5-dibromosalicylanilide (077402)	0.04%
3,4',5-tribromosalicylanilide (077404)	0.16%
ethyl alcohol (001501)	55.53%
methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20% (069129)	0.50%
	56.23%

000257-00293 005590-00065 025023-00001

4',5-dibromosalicylanilide (077402)	0.04%
3,4',5-tribromosalicylanilide (077404)	0.16%
ethyl alcohol (001501)	62.75%
methyldodecylbenzyl trimethyl ammonium chloride 80% and methyldodecylxylylene bis(trimethyl ammonium chloride) 20% (069129)	0.50%
	63.45%

000385-00063

&200.3619 0.36% pressurized liquid

3,4',5-tribromosalicylanilide (077404)	0.3600%
ethyl alcohol (001501)	54.8100%
o-phenylphenol (064103)	0.1400%
4-chloro-2-cyclopentylphenol (064202)	0.0256%
	55.3356%

000334-00296

&200.7019 0.7% pressurized liquid

4',5-dibromosalicylanilide (077402)	0.35%
3,4',5-tribromosalicylanilide (077404)	0.35%
ethyl alcohol (001501)	54.81%
o-phenylphenol (064103)	0.14%
N-lauryl diethylenetriamine (079055)	0.35%
	56.00%

006018-00013

&201.0019 1% pressurized liquid

4',5-dibromosalicylanilide (077402)	0.45%
3,4',5-tribromosalicylanilide (077404)	0.55%
isopropanol (047501)	28.00%
	29.00%

000257-00210

REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)
In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Identity of Ingredients	TGAI	R	[X]	[ ]		6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	[X]	[ ]		6 Months
61-3 - Discussion of Formation of Impurities	TGAI	R	[X]	[ ]		6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	R	[X]	[ ]		12 Months
62-2 - Certification of Limits	TGAI	R	[X]	[ ]		12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	R	[X]	[ ]		12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	[ ]	[X]		
63-3 - Physical State	TGAI	R	[ ]	[X]		
63-4 - Odor	TGAI	R	[ ]	[X]		
63-5 - Melting Point	TGAI	R	[X]	[ ]		6 Months
63-6 - Boiling Point	TGAI	N/A	[ ]	[X]		

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS

uideline Citation and ıme of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below 1/
158.120 Product Chemistry (Continued)						
'hysical and Chemical Characteristics Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[X]	[ ]		6 Months
63-8 - Solubility	TGAI or PAI	R	[ ]	[X]		
63-9 - Vapor Pressure	PAI	R	[ ]	[X]	2	
63-10 - Dissociation constant	PAI	R	[ ]	[X]	2	
63-11 - Octanol/water partition coefficient	PAI	R	[ ]	[X]	2	
63-12 - pH	TGAI	R	[ ]	[X]	2	
63-13 - Stability	TGAI	R	[ ]	[X]		

TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 6 Month Due Date is June 30, 1986.
- 12 Month Due Date is December 31, 1986.

2/ These physical/chemical property data requirements are not required to support the registration of products under this standard due to the minimal environmental impact of this chemical.

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,5-DBS; 4'5-DBS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Identity of Ingredients	TGAI	R	[X]	[_]	_____	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	[X]	[_]	_____	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	R	[X]	[_]	_____	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	R	[X]	[_]	_____	12 Months
62-2 - Certification of Limits	TGAI	R	[X]	[_]	_____	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	R	[X]	[_]	_____	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	[X]	[_]	_____	6 Months
63-3 - Physical State	TGAI	R	[X]	[_]	_____	6 Months
63-4 - Odor	TGAI	R	[X]	[_]	_____	6 Months
63-5 - Melting Point	TGAI	R	[X]	[_]	_____	6 Months
63-6 - Boiling Point	TGAI	N/A	[_]	[X]	_____	

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,5-DBS; 4'5-DBS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	[X]	[ ]		6 Months
63-8 - Solubility	TGAI or PAI	R	[X]	[ ]		6 Months
63-9 - Vapor Pressure	PAI	R	[ ]	[X]	2	
63-10 - Dissociation constant	PAI	R	[ ]	[X]	2	
63-11 - Octanol/water partition coefficient	PAI	R	[ ]	[X]	2	
63-12 - pH	TGAI	R	[ ]	[X]	2	
63-13 - Stability	TGAI	R	[X]	[ ]		6 Months

TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 6 Month Due Date is June 30, 1986.
- 12 Month Due Date is December 31, 1986.

2/ These physical/chemical property data requirements are not required to support the registration of products under this standard due to the minimal environmental impact of these chemicals.

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	I	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	I	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	I	No		Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	I	No		No4/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding : - Rodent, and	TGAI	I	No		Reserved5/	15 Months
- Non-rodent (Dog)					Reserved5/	18 Months
82-2 - 21-Day Dermal - Rabbit	TGAI	I	No		Yes	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	I	No		Reserved5/	15 Months
82-4 - 90-Day Inhalation: - Rat	TGAI	I	No		Reserved5/	15 Months
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	I	No		No4/	
-Mammal					No4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.135 Toxicology - Continued					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species:	TGAI	I	No		
- Rodent, and					Reserved5/ 50 Months
- Non-rodent (Dog)					Reserved5/ 50 Months
83-2 - Oncogenicity - 2 species:	TGAI	I	No		
- Rat (preferred), and					Reserved5/ 50 Months
- Mouse (preferred)					Reserved5/ 50 Months
83-3 - Teratogenicity - 2 species:	TGAI	I	No		
- Rat					Yes 15 Months
- Rabbit					Yes 15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	I	No		Reserved5/ 39 Months
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	I	No		Yes 9 Months
84-2 - Structural Chromosomal Aberration	TGAI	I	No		Yes 12 Months
84-4 - Other Genotoxic Effects	TGAI	I	No		Reserved5/ 12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.135 Toxicology - Continued					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	I	No		Reserved5/ 24 Months
Exposure Data	TGAI	TB	No		Yes6/ 18 Months
Leachability Data	TGAI	TB	No		Yes7/ 18 Months
Dermal Penetration	TGAI	TB	No		Yes8/ 18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

§158.135 Toxicology - Continued

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor; TB=Textile Biocide.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document....
- 9 Month Due Date is May 31, 1986.
- 12 Month Due Date is August 31, 1986.
- 15 Month Due Date is November 30, 1986.
- 18 Month Due Date is February 28, 1987.
- 24 Month Due Date is August 31, 1987.
- 39 Month Due Date is November 30, 1988.
- 50 Month Due Date is October 31, 1989.

4/ This chemical is not an organophosphorous compound nor does it produce cholinesterase inhibition.
5/ Depending on the outcome of the SPECIAL TESTING data required, the Agency will address these data requirements.
6/ The data requirements are to be based on actual exposure, therefore the Registrant is requested to provide exposure estimates or determinations on a mixture of all three chemicals under the conditions of use.
7/ The data requirements are to be based on actual exposure, therefore the Registrant is requested to provide leachability data on a mixture of all three chemicals at the highest percentage recommended on the label if the intended use has the potential for direct body contact. Protocols to be used by the Registrant must be submitted to the Agency prior to conducting the study.
8/ The data requirements are to be based on actual exposure, therefore the Registrant is requested to provide dermal penetration data for a mixture of all three chemicals at the highest percentage recommended on the label unless under the conditions of use he has shown that there is no potential for leaching. Protocols must be submitted to the Agency prior to conducting the study.

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	I	No		Yes4/	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	I	No		Yes4/	9 Months
161-3 - On soil	TGAI or PAIRA	I	No		No	
161-4 - In Air	TGAI or PAIRA	I	No		No	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	I	No		No	
162-2 - Anaerobic Soil	TGAI or PAIRA	I	No		No	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	I	No		No	
162-4 - Aerobic Aquatic	TGAI or PAIRA	I	No		No	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	I	No		No	
163-2 - Volatility (Lab)	TEP	I	No		No	
163-3 - Volatility (Field)	TEP	I	No		No	

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.130 Environmental Fate - Continued					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	I	No		No
164-2 - Aquatic (Sediment)	TEP	I	No		No
164-3 - Forestry	TEP	I	No		No
164-4 - Combination and Tank Mixes					
164-5 - Soil, Long-term	TEP	I	No		No
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	I	No		No
165-2 - Rotational Crops (Field)	TEP	I	No		No
165-3 - Irrigated Crops	TEP	I	No		No
165-4 - In Fish	TGAI or PAIRA	I	No		No
165-5 - In Aquatic Non-Target Organisms	TEP	I	No		No

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

§158.130 Environmental Fate - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
° 9 Month Due Date is September 30, 1986.
4/ These data are required because of the Aquatic Impact (direct discharge) use.

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	I	No		No	
71-2 - Avian Subacute Dietary Toxicity	TGAI	I	No		Yes4/	6 Months
71-3 - Wild Mammal Toxicity	TGAI	I	No		No	
71-4 - Avian Reproduction	TGAI	I	No			
- Upland Game Bird, and					No	
- Waterfowl					No	
71-5 - Simulated Field Testing	TEP	I	No			
- Mammals, and					No	
- Birds					No	
- Actual Field Testing	TEP	I	No			
- Mammals, and					No	
- Birds					No	

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity - Coldwater Fish Species, and	TGAI	I	No		Yes	6 Months
- Warmwater Fish Species					Yes	6 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	I	No		Yes	6 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	I	No			
- Fish					No	
- Mollusk					No	
- Shrimp					No	
72-4 - Fish Early Life Stage, and	TGAI	I	No		No	
- Aquatic Invertebrate Life-Cycle					No	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued					
72-5 - Fish - Life-Cycle	TGAI	I	No		No
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	I	No		
- Crustacean					No
- Fish					No
- Insect Nymph					No
- Mollusk					No
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	I	No		No
- Actual Field Testing -Aquatic Organisms					No

TABLE A
GENERIC DATA REQUIREMENTS FOR 3,4',5-TBS; 3,5-DBS; 4',5-DBS

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
° 6 Month Due Date is June 30, 1986.
4/ Only one species is required.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	[X]	[ ]		6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	[X]	[ ]		6 Months
61-3 - Discussion of Formation of Impurities	MP	R	[X]	[ ]		6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	R	[X]	[ ]		12 Months
62-2 - Certification of Limits	MP	R	[X]	[ ]		12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	R	[X]	[ ]		12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	R	[X]	[ ]		6 Months
63-3 - Physical State	MP	R	[X]	[ ]		6 Months
63-4 - Odor	MP	R	[X]	[ ]		6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	[X]	[ ]		6 Months
63-12 - pH	MP	CR	[ ]	[X]	2	
63-14 - Oxidizing or Reducing Action	MP	CR	[X]	[ ]		6 Months
63-15 - Flammability	MP	CR	[X]	[ ]		6 Months
63-16 - Explodability	MP	R	[X]	[ ]		6 Months
63-17 - Storage Stability	MP	R	[X]	[ ]		15 Months
63-18 - Viscosity	MP	CR	[ ]	[X]	3	
63-19 - Miscibility	MP	N/A	[ ]	[X]		
63-20 - Corrosion Characteristics	MP	R	[X]	[ ]		15 Months

MP = Manufacturing-use Product; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 6 Month Due Date is June 30, 1986.
- 12 Month Due Date is December 31, 1986.
- 15 Month Due Date is March 31, 1987.

2/ Not required due to the minimal environmental impact of these chemicals.

3/ Not required unless the product is a liquid.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Acute Oral Toxicity - Rat	MP	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	No		Reserved3/	9 Months

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
° 9 Month Due Date is September 30, 1986.
3/ Depending on the outcome of the SPECIAL TESTING data required, the Agency will address this data requirement.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	EP	R	[X]	[ ]		6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	R	[X]	[ ]		6 Months
61-3 - Discussion of Formation of Impurities	EP	R	[X]	[ ]		6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	EP	R	[X]	[ ]		12 Months
62-2 - Certification of Limits	EP	R	[X]	[ ]		12 Months
62-3 - Analytical Methods to Verify Certified Limit	EP	R	[X]	[ ]		12 Months
Physical and Chemical Characteristics						
63-2 - Color	EP	R	[X]	[ ]		6 Months
63-3 - Physical State	EP	R	[X]	[ ]		6 Months
63-4 - Odor	EP	R	[X]	[ ]		6 Months

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Time Frames Listed Below 1/
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	EP	R	[X]	[ ]		6 Months
63-12 - pH	EP	CR	[X]	[ ]		6 Months
63-14 - Oxidizing or Reducing Action	EP	CR	[X]	[ ]		6 Months
63-15 - Flammability	EP	CR	[X]	[ ]		6 Months
63-16 - Explodability	EP	R	[X]	[ ]		6 Months
63-17 - Storage Stability	EP	R	[X]	[ ]		15 Months
63-18 - Viscosity	EP	CR	[X]	[ ]		6 Months
63-19 - Miscibility	EP	CR	[X]	[ ]		6 Months
63-20 - Corrosion Characteristics	EP	R	[X]	[ ]		15 Months

EP = End-Use Product; R = Required; CR = Conditionally Required
1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 6 Month Due Date is June 30, 1986.
- 12 Month Due Date is December 31, 1986.
- 15 Month Due Date is March 31, 1987.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Acute Oral Toxicity - Rat	EP	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	EP	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	EP	No		Yes3/	9 Months
81-4 - Primary Eye Irritation - Rabbit	EP	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	EP	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	EP	No		Yes4/	9 Months

1/ Composition: EP = End-Use Product.
2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
° 9 Month Due Date is September 30, 1986.
3/ Required if the product is to be used as an aerosol.
4/ Required if repeated dermal exposure is expected.

TABLE C

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 3,4',5-TBS; 3,5-DBS; 4',5-DBS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)?	Time Frame for Data Submission 3/
§158.160 Product Performance					
Efficacy of Antimicrobial Agents					
91-2 - Products For Use On Hard Surfaces	TEP	No		Yes2/	6 Months
91-3 - Products Requiring Confirmatory Data	TEP	No		Yes2/3/	6 Months

1/ Composition: TEP = Typical end-use Product

2/ Data must be submitted for products bearing a claim to control microorganisms that pose a threat to human health and whose presence cannot be readily observed by the user. Such microorganisms include, but are not limited to, microorganisms infectious to man in any area of the inanimate environment. Products not meeting this requirement need not submit efficacy data at this time. However, all registrants must have data available to show that their products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, when necessary, submission of efficacy data for any proposed or registered pesticide product.

3/ This is to show similarity to products with sufficient data.

4/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.

° 6 Month Due Date is June 30, 1986.

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to all products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

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

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4, IV-5, and IV-6 to determine the storage and disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing (Brominated Salicylanilide) as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data (See Tables B).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten

text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing (Brominated Salicylanilide) in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing (Brominated Salicylanilide) alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1), if applicable (if Table C lists required product-specific data).

c. Two copies of any required product-specific data, if applicable (if Table C lists required product-specific data).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing (Brominated Salicylanilide) either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

Applications and other required information should be submitted to the following address:

A. E. Castillo
Product Manager (32)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-3964

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the 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. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

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 the 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 numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; 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. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

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 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. 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 the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(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 (Accession Numbers). The final element in the trailing parentheses 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.

REGISTRATION STANDARD BIBLIOGRAPHY
Citations Reviewed but Found to be Non-Conclusive of the Registration Standard Guidelines Under the Brominated Salicylanilide Standard

00042949 Dow Chemical Company (19??). Tuasal® (Unpublished study received on unknown date under unknown admin, no.; CDL: 106266-A)

00043906 Hexcel Corporation (19??). Temasept II (TBS): Composition, Manufacturing and Specifications (Unpublished study received on September 4, 1959 under unknown admin. no.; CDL: 106241-AD)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products)

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval 2070-0057 (expires 5/31/86)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1 I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm")

2 My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s).

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4 My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX IV -1

§ 162.10 Labeling requirements

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following.

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for

whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section.

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section, and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background, and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices.

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed", and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4)

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for • • •," "Distributed by • • •," or "Sold by • • •" to show that the name is not that of the producer.

(d) *Net weight or measure of contents* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg No." The registration number shall be set in type of a size and style similar to

other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency

(f) *Producing establishments registration number* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients, and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label. "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups, those required on the front panel of the labeling and those which may appear elsewhere Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2 000 thru 20 000	Greater than 20 000
Eye effects	Corrosive corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days irritation persisting for 7 days	No corneal opacity irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment—(A) Toxicity Category I* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the

basis of oral, inhalation or dermal toxicity The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word all capitals	Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral inhalation or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed (inhaled or absorbed through skin) Do not breathe vapor (dust or spray mist) Do not get in eyes on skin or on clothing (Front panel statement of practical treatment required)	Corrosive causes eye and skin damage (or skin irritation) Do not get in eyes on skin, or on clothing Wear goggles or face shield and rubber gloves when handling Harmful or fatal if swallowed (Appropriate first aid statement required)
II	May be fatal if swallowed (inhaled or absorbed through the skin) Do not breathe vapors (dust or spray mist) Do not get in eyes on skin or on clothing (Appropriate first aid statements required)	Causes eye (and skin) irritation Do not get in eyes on skin, or on clothing Harmful if swallowed (Appropriate first aid statement required)
III	Harmful if swallowed (inhaled or absorbed through the skin) Avoid breathing vapors (dust or spray mist) Avoid contact with skin (eyes or clothing) (Appropriate first aid statement required)	Avoid contact with skin eyes or clothing In case of contact immediately flush eyes or skin with plenty of water Get medical attention if irritation persists
IV	(No precautionary statements required)	(No precautionary statements required)

(ii) *Environmental hazards* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows

Flash point	Required text
(A) Pressurized Containers	
Flash point at or below 20° F if there is a flashback at any valve opening.	Extremely flammable Contents under pressure Keep away from fire sparks and heated surfaces Do not puncture or incinerate container Exposure to temperatures above 130° F may cause bursting
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable Contents under pressure Keep away from heat sparks, and open flame Do not puncture or incinerate container Exposure to temperatures above 130° F may cause bursting
All other pressurized containers	Contents under pressure Do not use or store near heat or open flame Do not puncture or incinerate container Exposure to temperatures above 130° F may cause bursting
(B) Nonpressurized Containers	
At or below 20° F	Extremely flammable Keep away from fire sparks and heated surfaces
Above 20° F and not over 80° F	Flammable Keep away from heat and open flame
Above 80° F and not over 150° F	Do not use or store near heat or open flame

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular " and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes.

(*3*) The product will not come into the hands of the general public except after incorporation into finished products, and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment, and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that.

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes,

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered, and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required. "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975, 40 FR 32329, Aug 1, 1975, 40 FR 36571, Aug 21, 1975, as amended at 43 FR 5786, Feb 9, 1978]

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)

Active Ingredients:

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)

Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)

Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)

Active Ingredients continued:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)

Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11)
Vinyl chloride
Xylene

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.