I. Overview
   A. Active Ingredient Overview
      • Common Name: Kaolin
      • Chemical Name: Kaolin
      • Chemical Formula: \( \text{AL}_4\text{Si}_4\text{O}_{10} \text{(OH)}_8 \)
      • Chemical Family: Aluminosilicate minerals
      • Trade and Other Names: Kaolin
      • CAS Registry Number: 13332-58-7
      • OPP Chemical Code: 100104
      • Basic Manufacturer:
        Engelhard Corporation
        101 Wood Avenue
        Selin, NJ 08830

   B. Use Profile

   The following is information on the proposed uses with an overview of use sites and application methods.

   Type of Pesticide: Repellent / protectant, aids in control of damage by insects, mites, fungi, and bacteria.

   Use Sites: Agricultural crops.

   Target Pests: Insects, mites, fungi and bacteria.

   Formulation Types: Wettable powder.

   Method and Rates of Application: The two end-use products M-96-018 Kaolin, M-97-002 Kaolin containing 98.8%, 99.4% of kaolin are to be mixed (with agitation) into 4 gallons of methanol (98% purity) to form a slurry, then added to 100 gallons of water. These proportions may be proportionally scaled up or down as needed. The mixture is then applied (with gentle agitation to keep the product in suspension) using a standard recirculating sprayer. The product will be applied at rates of 6.25 to
25 lbs/A to field and vegetable crops, 25 to 175 lbs/A to tree fruit crops, and 12.5 to 37.5 lbs/A to small fruit crops to help control of damage by insects, mites, fungi, and bacteria. Proposed label for M-97-009 Kaolin is identical to the proposed label for M-96-018 in regard to precautionary statements, use sites, and use rates. However, M-97-009 Kaolin is directly mixed with water (no methanol is used in the spray preparation), and it is recommended for use to help control damages by insects and mites.

**Use Practice Limitations:** None

**Timing:** Application should be made prior to optimum conditions for disease or insect cycle occur. Repeat at 7-14 day intervals.

### C. Estimated Usage of Pesticide

Limited use of M-97-018 Kaolin (containing 98.8% kaolin) under Experimental Use Permit (EUP) 70060-EUP-1, issued in May of 1997.

### D. Data Requirements

The mammalian toxicology and ecological effects data requirements for kaolin have been fulfilled. Product analysis data requirements are adequately satisfied. The data requirements for granting this registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of this chemical and recommends an unconditional registration of this new active ingredient for the proposed uses.

### E. Regulatory History

In August of 1997, the Agency received an application from Engelhard Corporation to register three end-use products M-96-018, M-97-002, and M-97-009 Kaolin containing 98.8%, 99.4%, and 100% of anhydrous kaolin. This action involves end-use products only. There is no technical, and kaolin products will be manufactured by an integrated process.

A notice of receipt of the application for registration of kaolin as a new active ingredient was published in the Federal Register on October 30, 1997 (62 FR 58729), with a 30-day comment period. As a result of this publication, two comments were received regarding the registration of kaolin solely as a pesticide product active
ingredient, and the exemption of kaolin from the requirements of FIFRA under FIFRA section 25(b). After reviewing the issues raised in regard to this action, BPPD offers the following observations:

i. EPA is not registering kaolin solely as a pesticide active ingredient. Kaolin can still be used as an inert ingredient in formulated products. Kaolin is considered a valuable inert ingredient that is widely used in several food and none food products. As a result, EPA has no intention of classifying kaolin as an active ingredient only, and restricting its numerous uses as an inert.

ii. If kaolin is registered as an active ingredient, applicants who want to use it as an inert in the formulation of their product will not have to pay data compensation for Engelhard Corporation. Inert ingredients are not subject to data compensation under FIFRA section 3(c).

iii. BPPD believes that kaolin meets the criteria for exemption from the requirements of FIFRA under section 25(b). As a result, kaolin has been proposed to be considered for section 25(b). A proposed rule that adds this compound to the list of potential chemicals that would benefit from FIFRA 25(b), may be published by the end of this year.

F. Classification

OPP's Biochemical Classification Committee had reviewed kaolin along with other clays. The Committee has determined that these naturally occurring compounds have a non-toxic mode of action. However, the mode of action will be difficult to prove. In addition, a strict interpretation of the biochemical pesticide may exclude these products which are not organic or inorganic chemicals associated with physiological processes of a living organism. In the regulations, examples listed as biochemical pesticides, all are physiological active substances. Although kaolin may not technically fit the biochemical pesticide definition, it should be eligible for waivers for much of the data requirements because of its natural occurrence and predicted non toxic mode of action.

G. Food Clearances/Tolerances

Kaolin is exempted from the requirement of a tolerance for residues when used on or in or on food commodities to aid control insects, fungus, and bacterial damage to plant crops (food/feed use) (63 FR 9427, February 25, 1998)

II. Science Assessment

A. Physical/Chemical Properties Assessment

All product chemistry data requirements for kaolin technical grade active ingredient are satisfied.
0. **Product Identity and Mode of Action**

   a. **Product Identity:**

   Kaolin is a white, nonporous, nonswelling, natural aluminosilicate mineral with the chemical formula \( \text{Al}_4\text{Si}_4\text{O}_{10}(\text{OH})_8 \). Kaolin is one of the most highly divided and highly refined naturally occurring minerals. Median particle size of commercial products vary between 0.1-10 microns. Kaolin is chemically inert. Its hydrophilic surface allows kaolin to be easily dispersed in water at neutral pH values of 6-8. Common physical properties of kaolin are: platy shape, high brightness (80-95), specific gravity 2.58-2.63, refractive index 1.56-1.62, and Mohs hardness 2-3.

   b. **Mode of Action:**

   Kaolin has a nontoxic mode of action. It acts as a repellent / protectant, and forms a barrier film to protect plants from insects, mites and disease.

1. **Food Clearances/Tolerances**

   In the Federal Register of November 26, 1997 ([62 FR 63168](https://fr.dtic.mil/dtic/tr/fulltext/u2/a404302.pdf)), EPA issued a notice pursuant to section 408 (d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition for the new active ingredient kaolin (PP# 7E04908) by Engelhard Corporation. The notice included a summary of the petition prepared by the petitioner. The summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested the establishment of an exempt tolerance for residues of kaolin in or on all food commodities.

   Prior to the current petition request, BPPD supported the petition for temporary tolerance exemption (PP# 7G4793) for kaolin. The exemption from a temporary tolerance for kaolin on all food commodities was granted for purposes of an experimental use permit ([62 FR 19683](https://fr.dtic.mil/dtic/tr/fulltext/u2/a404302.pdf), April 23, 1997).

2. **Physical And Chemical Properties Assessment**

   The data requirements for physical and chemical characteristics that support the registration are summarized in Table 1. Since kaolin is manufactured by
an integrated process, this information will apply towards the generic data requirements for kaolin.

Table 1. Product chemistry data requirements

<table>
<thead>
<tr>
<th>GUIDELINE NO.</th>
<th>STUDY</th>
<th>RESULTS</th>
<th>MRID NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>151B-10</td>
<td>Product identity; Manufacturing process; Discussion of formulation of unintentional ingredients</td>
<td>Submitted data satisfy the data requirements for product identity, manufacturing process, and discussion of formation of impurities</td>
<td>44143801</td>
</tr>
<tr>
<td>151B-11</td>
<td>Analysis of samples</td>
<td>Submitted data satisfy the data requirements for analysis of samples</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-12</td>
<td>Certification of limits</td>
<td>Limits listed in the CSF are adequate CSF</td>
<td></td>
</tr>
<tr>
<td>151B-17(a)</td>
<td>Phys</td>
<td>White</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(b)</td>
<td>Physical State</td>
<td>Powder</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(c)</td>
<td>Odor</td>
<td>None</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(d)</td>
<td>Melting point</td>
<td>1800°C</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(e)</td>
<td>Boiling point</td>
<td>N/A</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(f)</td>
<td>Density/Specific gravity</td>
<td>2.5 - 2.7</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(g)</td>
<td>Solubility</td>
<td>Insoluble</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(h)</td>
<td>Vapor Pressure</td>
<td>N/A</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(i)</td>
<td>pH</td>
<td>5 - 7</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(j)</td>
<td>Stability</td>
<td>Stable</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(k)</td>
<td>Flammability</td>
<td>N/A</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(l)</td>
<td>Storage stability</td>
<td>Indefinite</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(m)</td>
<td>Viscosity</td>
<td>N/A</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(n)</td>
<td>Miscibility</td>
<td>N/A</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(o)</td>
<td>Corrosion characteristics</td>
<td>None-corrosive</td>
<td>44143802</td>
</tr>
<tr>
<td>151B-17(p)</td>
<td>Octanol/water partition coef.</td>
<td>N/A</td>
<td>44143802</td>
</tr>
</tbody>
</table>

B. Human Health Assessment

The information submitted supports the lack of toxicity of kaolin based on its long history of use by humans without any indication of deleterious effects. Kaolin is a naturally occurring mineral found in huge deposits worldwide. It is used as an
indirect food additive for paper / paper board dry food contact, adhesives, polymeric coatings, rubber articles, and cellophane. Kaolin is used as a cosmetic in face powders, face masks, and face packs. Kaolin is used in health products and toiletries, toothpaste, and antiperspirants. Kaolin can be used directly in foods as an anti-caking agent (up to 2.5%). Kaolin has GRAS (Generally Recognized as Safe) status under 21 CFR 186.1256 and is generally recognized as safe (As an indirect human food ingredient with no limitation other than current good manufacturing practice.)

The overall toxicological risk from human exposure to kaolin is considered negligible. As a result, most mammalian toxicology studies were waived.

0. **Toxicology Assessment**

Adequate mammalian toxicology data are available and support registration of the active ingredient kaolin

a. **Acute Toxicity**

The submitted toxicity studies are acceptable for these new registrations. No additional toxicity data are required. The data reported in the acute oral toxicity studies demonstrated that the acute oral LD50 for Kaolin in rats is >5000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the acute dermal toxicity study demonstrated that the acute dermal LD50 for kaolin in rats is >5000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the primary eye irritation study demonstrate that the test substance was minimally irritating. Kaolin was not corrosive and all eye irritation effects cleared within 72 hours postdosing; Toxicity Category III. The data reported in the primary skin irritation study demonstrated that the test substance caused no dermal irritation in rabbits treated with 0.5 g kaolin for 4 hours. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV.

b. **Mutagenicity and Developmental Toxicity**

Waivers for mutagenicity and developmental toxicity were requested. The Agency granted these waivers based on long use history of
kaolin in food and food products without any indication of deleterious effects.

Mammalian toxicity data submitted are summarized in Table 2. Since kaolin is produced by an integrated process, this information will apply towards the generic data requirements for kaolin.

Table 2. Toxicity data requirements

<table>
<thead>
<tr>
<th>GUIDELINE NO.</th>
<th>STUDY</th>
<th>RESULTS</th>
<th>MRID NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>152-10</td>
<td>Acute oral toxicity</td>
<td>Toxicity Category IV</td>
<td>44356701 44356705</td>
</tr>
<tr>
<td>152-11</td>
<td>Acute dermal toxicity</td>
<td>Toxicity Category IV</td>
<td>44356702</td>
</tr>
<tr>
<td>152-12</td>
<td>Acute inhalation toxicity</td>
<td>Toxicity Category IV</td>
<td>44400701</td>
</tr>
<tr>
<td>152-13</td>
<td>Primary eye irritation</td>
<td>Toxicity Category III</td>
<td>44356704</td>
</tr>
<tr>
<td>152-14</td>
<td>Primary dermal irritation</td>
<td>Toxicity Category IV</td>
<td>44356703</td>
</tr>
<tr>
<td>152-15</td>
<td>Dermal sensitization</td>
<td>Waived</td>
<td></td>
</tr>
<tr>
<td>152-16</td>
<td>Hypersensitivity incidents</td>
<td>Waived</td>
<td></td>
</tr>
<tr>
<td>152-17</td>
<td>Genotoxicity - <em>Salmonella typhimurium</em> gene mutation assay</td>
<td>Waived</td>
<td></td>
</tr>
<tr>
<td>152-18</td>
<td>Cellular immune response</td>
<td>Waived</td>
<td></td>
</tr>
</tbody>
</table>

**c. Subchronic Toxicity**

Waivers for subchronic toxicity were requested. The waivers were granted based on the long use history of kaolin without any indication of deleterious effects.

**d. Chronic Exposure and Oncogenicity Assessment**
Chronic exposure studies are conditionally required to support non-food uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required to support non-food uses only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic changes. The triggers for chronic exposure and oncogenicity studies were not met.

e. **Effects on the Immune and Endocrine Systems**

Immunotoxicity studies and information on the endocrine effects of this compound were waived based on low exposure, lack of toxicity in the submitted exposure studies, and the long history of safe use of kaolin in food, pharmaceuticals and cosmetics.

1. **Dose Response Assessment**

No toxicological endpoints are identified.

2. **Dietary Exposure and Risk Characterization**

Dietary exposure of kaolin via food or water is difficult to estimate due to the widespread use of kaolin in thousands of products, in food, pharmaceuticals, cosmetics, in addition to use as an inert in pesticide formulations. Kaolin is an inert mineral and has no known toxicological effects. In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population including infants and children.

3. **Occupational, Residential, School and Day Care Exposure and Risk Characterization**

No uses in residential areas are stated in proposed labels for kaolin. Therefore, humans exposure is not expected in these area.

a. **Occupational Exposure and Risk Characterization**

There is a possibility for dermal, eye and inhalation exposure, but risk to applicators is mitigated as long as the product is used according to label directions. The Agency has considered kaolin in
light of the safety factors in the Food Quality Protection Act (FQPA) of 1996 and has made a determination of reasonable certainty of no harm to the U. S. population in general, and to infants and children in particular.

b. **Residential, School and Day Care Exposure and Risk Characterization**

No indoor residential, school, or day care uses currently appear on proposed labels.

4. **Drinking Water Exposure and Risk Characterization**

Because of its insolubility in water, exposure to kaolin in drinking water is not expected.

5. **Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children**

Dietary risk from exposure to kaolin is difficult to estimate due to the use of kaolin in thousands of products. Kaolin is an inert naturally occurring mineral, and it has no known toxicological effects. From its long history of use, there is no reported evidence or reason to believe that infants and children would be more sensitive to kaolin than adults.

6. **Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation**

Aggregate exposure would primarily occur in the mixer/loader/applicator subpopulation via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for kaolin showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category IV), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.
7. **Cumulative Effects**

Kaolin is not toxic and therefore there would be no expected cumulative effects from common mechanisms of toxicity. In addition, kaolin is naturally occurring, and it is used in thousands of products. An exact cumulative exposure is not necessary due to the non-toxic nature of kaolin.

C. **Environmental Assessment**

0. **Ecological Effects Hazard Assessment**

Data waivers for avian acute and oral toxicity were requested and supported based on the current widespread agricultural use of kaolin clay as an inert, and the lack of reported avian toxicity incidents associated with this use. The submitted honeybee toxicity and spider monitoring studies are acceptable in support of these new registrations. No additional data are required. The data reported in the honeybee acute contact toxicity study demonstrated that there were no adverse effects resulting from treatment with kaolin. A single mortality observed in the kaolin-treated bees was unrelated to the treatment. The 48-hour LD$_{50}$ was determined to be $>100 \mu g$ kaolin/bee and the no effect dose was determined to be $100 \mu g$ kaolin/bee. The data reported in the honeybee acute dietary toxicity study demonstrated that there were no adverse effects resulting from treatment with kaolin in the diet. The few observed mortalities in the kaolin-treated bees were unrelated to treatment with kaolin. The dietary LC$_{50}$ was estimated to be $>1000$ ppm kaolin, and the no observed effect concentration was estimated to be 1000 ppm kaolin.

The non-target insect/spider monitoring study in apple trees was inconclusive. The low and variable populations of predators (lady beetles, green lacewings, and spiders) precluded an assessment of the effects (if any) resulting from treatment with kaolin. However, based on data reported in companion studies on honey bees (see Conclusion 3 above), it is not likely that kaolin treatment would cause any adverse effects in non-target predators. Furthermore, additional field monitoring studies with non-target insect/spiders will probably not provide any new information. The Agency does not require any additional data on non-target insects/spiders.
TABLE 3. Non-Target Toxicity Studies - Tier I Guideline Requirements

<table>
<thead>
<tr>
<th>GUIDELINE NO.</th>
<th>STUDY</th>
<th>RESULTS</th>
<th>MRID NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>154-6</td>
<td>avian acute oral</td>
<td>Waived</td>
<td></td>
</tr>
<tr>
<td>154-7</td>
<td>avian dietary</td>
<td>Waived</td>
<td></td>
</tr>
<tr>
<td>154-8</td>
<td>freshwater fish LC_{50}</td>
<td>Waived</td>
<td></td>
</tr>
<tr>
<td>154-9</td>
<td>freshwater invertebrate LC_{50} (Daphnia magna)</td>
<td>LD_{50} &gt; 1000 ppm a.i.</td>
<td>44356707</td>
</tr>
<tr>
<td>154-11</td>
<td>Honeybee Acute Dietary</td>
<td>LD_{50} &gt;100 μg a.i./bee</td>
<td>44356706</td>
</tr>
<tr>
<td></td>
<td>Honeybee Acute Contact Insect predators</td>
<td>Inconclusive</td>
<td>44356708</td>
</tr>
</tbody>
</table>

1. **Environmental Fate and Ground Water Data**

The need for environmental fate and groundwater data (Tier II) was not triggered under current requirements (40 CFR Section 158.690(d)(2)(vii through xv) because of practically non-toxic results indicated in Tier I studies. Risk to nontarget species is minimal due to the use pattern, application methods, and mitigation of nontarget aquatic organism toxicity with appropriate precautionary label statements under "Environmental Hazards."

2. **Ecological Exposure and Risk Characterization**

A potential for exposure exists to nontarget insects, fish, and other wildlife with foliar spray applications. However, test results indicate that the compound is practically nontoxic to birds and freshwater fish, and, at most, slightly toxic to aquatic invertebrates. BPPD also believes that low toxicity, and mitigating label language present minimal to nonexistent risk to wildlife.

D. **Efficacy Data**

No efficacy data were required to be submitted to the Agency since no public health uses are involved.
III.

IV. Risk Management /Registration Eligibility
   A. Determination of Eligibility for Registration

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is
determined that (A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other materials required to be submitted comply with the
requirements of FIFRA; (C) it will perform its intended function without unreasonable
adverse effects on the environment; and (D) when used in accordance with
widespread and commonly recognized practice it will not generally cause
unreasonable adverse effects on the environment.

To satisfy criteria "A" above, kaolin is not expected to cause unreasonable adverse
effects when used according to label instructions. Criteria "B" is satisfied by the
current label and by the data presented in this document. It is believed that this new
pesticidal active ingredient will not cause any unreasonable adverse effects, will aid
in the control of damage to plants by insects, mites, fungi, and bacteria as claimed
satisfying Criteria "C". Criteria "D" is satisfied in that the toxicological properties of
this product are less toxic than any other conventional pesticide product currently in
use.

Therefore, kaolin is eligible for registration. Registered uses are listed in Table 4,
Appendix A.

B. Regulatory Position

0. Conditional/Unconditional Registration

All data requirements are fulfilled and BPPD recommends unconditional
registration of kaolin.

1. CODEX Harmonization

There are no Codex harmonization nor a known international tolerance
exemption for kaolin at this time. Kaolin is exempted from the requirement
of a tolerance for residues when used on or in or on food commodities to aid
control insects, fungus, and bacterial damage to plant crops (food/feed use)

2. Non-food Re/Registrations
There are no non-food issues at this time. The nonfood uses are listed in Appendix A, Table 4.

3. **Risk Mitigation**

Since there are no risk issues, risk mitigation measures are not required at this time for dietary risk, occupational and residential risk, risks to nontarget organisms (plants and wildlife), or ground and surface water contamination for these products. The product label will, however, bear Environmental Hazards text to mitigate any potential risk to aquatic species.

4. **Endangered Species Statement**

Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and their habitats. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

Prior to the implementation of the Endangered Species Protection Program, the Agency will not impose specific labeling on those pesticides that pose risks to threatened and endangered species and their habitats but will defer imposing specific labeling language until implementation of the Program.

**C. Labeling Rationale**

It is the Agency's position that the labeling for products containing kaolin complies with the current pesticide labeling requirements.

0. **Human Health Hazard**

   a. **Worker Protection Standard**

      Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse
must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in PR Notices 93-7 and 93-11. Unless otherwise specifically directed, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices.

After April 21, 1994, except as provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. Labeling also conforms to Worker Protection Safety standards where re-entry into sprayed fields must not take place until sprays have dried unless protective clothing is employed. Agricultural worker entry is not permitted during the restricted entry interval (REI) of 4 hours for kaolin products.

b. **Non-Worker Protection Standard**

There are no non-WPS human health hazard issues.

c. **Precautionary Labeling**

The Agency has examined the toxicological data base for kaolin products, and concluded that the proposed precautionary labeling (i.e. Signal Word, Statement of Practical Treatment and other label statements) adequately mitigates the risks associated with the proposed uses.
**End-Use product Precautionary Labeling:** For the three kaolin products, "CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. May cause irritation of the respiratory system. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing, and wash before reuse."

d. **Spray Drift Advisory**

An advisory statement is contained in the DIRECTIONS FOR USE statement for the two end-products. "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

1. **Environmental Hazards Labeling**

Provided the following statement is placed into the environmental hazards statement, the risk of kaolin is minimal to nonexistent to nontarget organisms including endangered species.

**End-Use Product Environmental Hazards Labeling:** "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of rinsing or equipment wash waters."

2. **Application Rate**

It is the Agency's position, that the labeling for the pesticide products containing kaolin complies with the current pesticide labeling requirements. The Agency has not required a maximum number of applications for the active ingredient. However, a specified maximum concentration of product per application is being required as follows:

The two end-use products M-96-018 Kaolin, and M-97-002 kaolin containing 98%, 99.4% of kaolin respectively, are to be mixed (with agitation) into 4 gallons of methanol (98% purity) to form a slurry, then added to 100 gallons of water. These proportions may be proportionally scaled up or down as needed. The product is then applied (with gentle agitation to keep the product in suspension) using a standard recirculating sprayer. The product will be applied at rates of 6.25 to 25 lbs/A to field and vegetable crops, 25 to 175 lbs/A to tree fruit crops, and 12.5 to 37.5 lbs/A to small fruit crops. Proposed labels for M-97-009 Kaolin (containing 100% of kaolin) is identical to the proposed label for M-96-018 in regard to precautionary statements, directions for use, use sites, and use rates. However, M-97-009 Kaolin is directly mixed with water (no methanol is used in the spray preparation),
and it is recommended for use to help control damage by insects and mites only.

**D. Labeling**

0. **Product name:** M-96-018 KAOLIN

   *Active Ingredient:* Kaolin 98.8%
   *Inert Ingredients* 1.2%

   **Total** 100.00%

1. **Product name:** M-97-002 KAOLIN

   *Active Ingredient:* Kaolin 94.4%
   *Inert Ingredients* 0.6%

   **Total** 100.00%

2. **Product name:** M-97-009 KAOLIN

   *Active Ingredient:* Kaolin 100.0
   *Inert Ingredients* 0.0%

   **Total** 100.00%

3. Signal word is "CAUTION". Eye irritation warning is appropriate.

4. The product shall contain the following information:
   - Product Name
   - Ingredient Statement
   - Registration Number
   - "Keep Out of Reach of Children"
   - Signal Word (CAUTION)

**V. Actions Required by Registrants**

Reports of incidences of adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

**VI. Appendix A**

M-96-018; M-97-002; M-97-009 kaolin
Use Sites

Beans (all), collards, garden beet, sugar beet, horseradish, radish, rutabagas, turnips, cotton, potato tomato, eggplant, pepper, lemons oranges, limes, apples, pears, loquats, crabapple, pears, quince, apricots, cherries, nectarines, peaches, plumes, prunes, blackberries, raspberries, dewberries and grapes.

Official date registered: March 17, 1998