diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the Federal Register of April 22, 1987 (52 FR 13305), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. The Agency has decided that no data, in addition to that described below, for isopropyl myristate will need to be submitted. The rationale for this decision is described below:

1. An acute oral toxicity study with an acute oral LD_{50} of greater than 42,400 mg/kg in mice and 14,000 mg/kg in rats.

- $\overline{2}$. The intraperitoneal acute toxicity studies with LD₅₀ of greater than 67,800 mg/kg in rats and greater than 42,800 mg/kg in mice.
- $\overline{3}$. An acute dermal study with LD₅₀ of greater than 67,829 mg/kg in rats and greater than 5,000 mg/kg in rabbits.
- 4. A rabbit primary eye irritation study using isopropyl myristate produced minimal irritation and cleared within 7 days.
- 5. A rabbit primary dermal irritation study showing minimal irritation.
- 6. A guinea pig dermal sensitization study producing no evidence of dermal sensitization.
- 7. A rat acute inhalation toxicity study with LC_{50} greater than 33–41 mg/liter in rats indicating that isopropyl myristate is of minimal concern.
- 8. A 4-week rabbit dermal subchronic study with applications of 16 to 47 percent isopropyl myristate in rabbits at 1,700 and 2,000 mg/kg did not produce any systemic toxicity.
- 9. A 12-week intramascular injection of 25 percent isopropyl myristate at 256 mg/kg in rats, 119 mg/kg in dogs, and 128-282 mg/kg in monkeys produced

minor local skin effects and no systemic toxicity effects.

- 10. Å 13-week inhalation study using 16 to 20 percent isopropyl myristate showed lung enlargements in guinea pigs at 224 mg/m³ and monkeys at 5.3 to 37 mg/m³.
- 11. Rabbit and mice dermal carcinogenicity studies showed that isopropyl myristate is not carcinogenic when applied chronically on the skin of mice at 3.4 mg/kg for 18 months and for 110 weeks and on rabbits at 68, 340, and 680 mg/kg for 160 weeks. A mixture of isopropyl myristate and isopropyl alcohol accelerated the carcinogenic activity of benzo-pyrene when applied on the skin of mice.
- 12. A metabolism study showed that isopropyl myristate is hydrolyzed to normal metabolic products, namely isopropyl alcohol and myristic acid.

13. Isopropyl myristate Ames Assay produced a negative result.

The Agency does not have data from two subchronic developmental toxicity and two mutagenicity studies which are part of the toxicology data typically required to be submitted in support of a tolerance exemption request. However, based upon isopropyl myristate's lack of carcinogenicity, mutagenicity (Ames Test) and low acute toxicity from oral, dermal, inhalation, or parenteral toxicity studies, the Agency does not believe that isopropyl myristate poses significant risks under the proposed conditions of use. No further studies are required. In addition, isopropyl myristate is likely metabolized to isopropyl alcohol, which is exempt from tolerance requirements under 40 CFR 180.1001 (c), (d), and (e), and myristic acid, which is an edible fatty acid.

Based upon the above information and review of its use, EPA has found that, when used in accordance with good agricultural practice, this ingredient is useful and a tolerance is not necessary to protect the public health. Therefore, EPA proposes that the exemption from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the

Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP-300376]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: January 23, 1995.

Lois Rossi,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows

Part 180—[Amended]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001 is amended in paragraphs (c) and (e) in the tables therein by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

(c) * * * * *