5. The 90-day dermal toxicity study with a NOEL of 20 mg/kg/day in rabbits and greater than 125 mg/kg/day in rats.

6. The developmental toxicity study in rabbits with a systemic maternal NOEL of 50 mg/kg/day and a developmental NOEL of > 200 mg/kg/day indicating no evidence of developmental effects.

7. The rat reproductive toxicity study with the systemic and developmental NOEL of 50 mg/kg/day and reproductive NOEL of > 250 mg/kg/day indicating no evidence of reproductive effects.

8. The rat chronic and carcinogenicity study with systemic NOEL of 50 mg/kg/day showing no evidence of carcinogenicity effects.

Based upon the above evaluation of the toxicological data which shows no evidence of carcinogenicity, mutagenicity (Ames Test), acute and subchronic dermal, developmental or reproductive toxicity of α-alkyl (C21-C₇₁)-ω-hydroxypoly (oxyethylene) and the expected dietary exposure, the Agency concludes that this chemical poses no significant risks under the proposed conditions of use and that no further data are required. In addition, these chemicals are similar to other ethoxylated alcohols [C₁₂₋₁₅polyethoxylated alcohols (CAS # 68131-40-8), C₁₂₋₂₀-ethoxylated alcohols (CAS # 68526-94-3) and C₁₂₋₁₈-ethoxylatedpropoxylated alcohol (CAS # 69227-21-0)], which have already been exempted from the requirement of a tolerance under 40 CFR 180.1001(c) or (d) based on data indicating no adverse toxicological effects. Furthermore, these chemicals are among those that the Agency has sufficient information to conclude that their current use patterns in pesticide products will not adversely affect public health and the environment and which have subsequently been reclassified from List 3 (inert ingredients of unknown toxicity) to List 4b (inert ingredients of minimal concern) (60 FR 35396, July 7, 1995). The α -alkyl (C_{21} - C_{71})- ω -hydroxypoly(oxyethylene) merely have a longer carbon chain, and the expected breakdown products are similar to the shorter extant ethoxylated alcohols. There is no reason to believe that there would be any toxicological concern for the longer carbon chain-length alcohols since these would most likely result in decreased absorption and toxicity. Furthermore, similar surfactants, i.e., ethoxylated fatty acids and their salts and esters, ethoxylated polyglycols,

ethoxylated amines, and others, are presently exempted from tolerances under 40 CFR 180.1001.

Based upon the information above, the toxicological data and physicochemical properties of α -alkyl (C_{21} - C_{71})- α -hydroxypoly(oxyethylene), and review of its use, the Agency 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, [PP 5E4540/P633]. 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 4:30 p.m. Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [PP 5E4540/P633] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

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, Reporting and recordkeeping requirements.

Dated: September 19, 1995.

Peter Caulkins,

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(d) is amended in the table therein by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * * (d) * * *