anticaking agent for animal feeds is safe when used in accordance with current good manufacturing practices.

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in 21 CFR 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before March 23, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 573.280 is revised to read as follows:

§ 573.280 Feed-grade calcium stearate and sodium stearate.

Feed-grade calcium stearate and sodium stearate may be safely used in an animal feed in accordance with the following prescribed conditions:

(a) Feed-grade calcium stearate and sodium stearate are the calcium or sodium salts of a fatty acid mixture that is predominately stearic acid. Associated fatty acids, including palmitic acid and minor amounts of lauric, myristic, pentadecanoic, margaric, arachidic, and other fatty acids may be contained in the mixture, but such associated fatty acids in aggregate do not exceed 35 percent by weight of the mixture. The fatty acids may be derived from feed-grade fats or oils.

(b) The additives meet the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) They are free of chick-edema factor.

(c) The additives are manufactured so that in aqueous solution they are exposed for 1 hour or longer to temperature in excess of 180 °F.

(d) They are used as anticaking agents in animal feeds in accordance with current good manufacturing practices.

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–4223 Filed 2–19–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MI58–01–7266; FRL–5967–3]

Approval and Promulgation of State Implementation Plans; Michigan

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This rulemaking finalizes the United States Environmental Protection Agency's (USEPA) disapproval of the State Implementation Plan (SIP) revision submitted by Michigan containing start-up, shutdown and malfunction (SSM) regulations which would apply generally to sources covered under the applicable SIP. This action is being taken under section 110 of the Clean Air Act (Act).

DATES: This final rule is effective March 23, 1998.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Kathleen D'Agostino at (312) 886–1767 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 886–1767.

SUPPLEMENTARY INFORMATION:

I. Background

On March 20, 1997 (62 FR 13357), the USEPA published a document proposing disapproval of a SIP revision containing Rules 336.1912, 336.1913 and 336.1914, which was submitted by the Michigan Department of Environmental Quality (MDEQ) on May 16 1996. Rule 336.1912 requires that a source be operated in a manner consistent with good air pollution control practices for minimizing emissions during start-ups, shutdowns and malfunctions, and contains notice and reporting requirements in the event of start-up, shutdown or malfunction. Rules 336.1913 and 336.1914 excuse excess emissions resulting from start-ups, shutdowns or malfunctions, providing that the notice and reporting requirements in Rule 336.1912 are met. The rationale for USEPA's proposed action is explained in the notice of proposed rulemaking and will not be restated here.

II. Public Comments/Response to Comments

This section summarizes the comments submitted during the public comment period for the notice of proposed rulemaking and provides USEPA's response to those comments. The comment period closed April 21, 1997. Adverse comments were received from the Michigan Department of

Environmental Quality, the Michigan Chamber of Commerce, the Michigan Manufacturers Association, General Motors Corporation and the American Automobile Manufacturers Association.

Comment: USEPA's proposed disapproval is not supported by section 110 of the Clean Air Act (CAA). There is no specific language in section 110 that provides the USEPA with the authority to disapprove Michigan's SSM rules. Section 110 contains no provisions that prohibit the type of exemption and affirmative defense contained in the SSM rules.

Response: It is true that section 110 does not explicitly address SSM regulations. However, under section 110 of the Act, USEPA is required to determine whether a SIP submission, *inter alia,* provides for the attainment and maintenance of the National Ambient Air Quality Standards (NAAQS). Because SIPs are developed to attain and maintain ambient-based standards, any emissions above the SIP-approved limits may cause or contribute to violations of the NAAQS. USEPA believes that SSM regulations which are too broadly drawn can threaten attainment and maintenance of the NAAQS. Therefore, EPA believes that it is reasonable to interpret section 110 to prohibit generally applicable SSM provisions.

In addition, § 110(a)(2)(A) of the Act requires that SIP submissions contain enforceable limitations. Enforceability deficiencies, i.e., overly broad bypass provisions and definitions of ''malfunction,'' are discussed further below. (See USEPA's response to the comment that Michigan's SSM rules are consistent with the 1983 memorandum from Kathleen Bennett.)

Comment: Because CAA regulations, e.g., 40 CFR part 63, already allow for protection which is broader than that proposed in the Michigan rules, the USEPA is without authority to proclaim that enforcement discretion is the only avenue for an SSM process to proceed. It is illogical to argue that Michigan's SSM rules do not comply with the CAA when CAA regulations provide for at least as broad protection against enforcement.

Response: The statutory and regulatory focus of NESHAPS (and NSPS) is fundamentally different from the SIP program and different policies apply, i.e., technology-based standards as opposed to the air quality objectives of section 110. The Bennett memoranda recognize that the attainment and maintenance of the NAAQS cannot be assured with overly-broad SSM provisions. EPA continues to believe that the health-based objective of SIPs make general SSM provisions unacceptable, even though such provisions may be appropriate for technology-based standards such as NESHAP and NSPS.

Comment: There is a substantive difference between the position set forth in the Bennett memoranda and the protections afforded by both 40 CFR 63 and the Michigan SSM rules. The promulgated Federal and State rules provide that there is no violation if the requirements of the rules are met. In contrast, the USEPA's memoranda position provides that there is a substantive violation of the CAA which then becomes subject to its enforcement discretion.

Response: The USEPA acknowledges that the Bennett memoranda recognize all periods of excess emissions as violations of the applicable SIP standard whereas periods of excess emissions occurring during start-ups, shutdowns or malfunctions may be excused under 40 CFR part 63 for NESHAPS. For the reasons discussed in response to the previous comment, USEPA believes that this is a reasonable distinction.

Comment: The USEPA misconstrues its authority under section 110 of the CAA. The United States Court of Appeals for the District of Columbia Circuit recently affirmed that the USEPA is not authorized under section 110 to dictate to states the methods to be used to achieve and maintain compliance with the National Ambient Air Quality Standards (NAAQS). Rather the D.C. Circuit recognized the relationship between the states and USEPA as one in which the states determine how best to regulate emission sources to achieve and maintain compliance with the NAAQS while USEPA is limited to determining whether each state's program will achieve the required air quality standards.

In promulgating the SSM statutory provisions and corresponding regulations, Michigan has exercised its power to ''determine which sources would be burdened by regulations and to what extent.'' Provided that attainment and maintenance of the NAAQS is the result of Michigan's overall implementation plan, the USEPA is not authorized, under section 110, to reject portions of Michigan's SIP that differ from the USEPA's enforcement policy.

Response: USEPA agrees that the CAA places primary responsibility upon the states to formulate requirements it deems appropriate to protect air quality. However, the CAA does not grant states unfettered discretion. Rather, the CAA and USEPA policy form a framework which states must work within when developing SIPs. (Some programs and requirements are expressly set forth in the CAA, e.g. inspection and maintenance, reasonably available control technology.) Furthermore, the Act charges USEPA with the determination as to whether the state's choices will result in attainment and maintenance of the NAAQS. For the reasons previously discussed, USEPA believes that the effect of Michigan's SSM regulations is to create uncertainty as to whether this statutory goal can be accomplished. In addition, § 110(a)(2)(A) of the Act requires that SIP submissions contain enforceable limitations. Enforceability deficiencies, i.e., overly broad bypass provisions and definitions of ''malfunction,'' are discussed further below. (See USEPA's response below to the comment that Michigan's SSM rules are consistent with the 1983 memorandum from Kathleen Bennett.)

Comment: Inconsistency with USEPA policy is not a valid reason for disapproval of a State Implementation Plan (SIP) revision. There is no reference to the Bennett memoranda, or any other policy, in section 110 of the CAA. Therefore, it is inappropriate to base the disapproval of Michigan's SSM rules on such policy memoranda. Statutory authority, and not policy memoranda, should be the basis for the disapproval.

Response: As noted previously, it is appropriate for USEPA to clarify regulations and statutes with written policies and guidance documents. In the context of rulemakings on SIP submissions, the public has an opportunity to comment and respond to USEPA's policies that interpret the relevant statutes and regulations. Through rulemaking actions, such as this, USEPA can determine whether to modify its policy or whether it still stands by its policy interpretation in light of any public comments. In this case, USEPA continues to support the policy established by the Bennet memoranda for the reasons stated in those memoranda and in this rulemaking action.

Comment: EPA's disapproval of Michigan's regulations, based on internal policy memoranda, is groundless. The SSM rules are the result of a publicly conducted work group, and were promulgated in accordance with all applicable State laws. The rationale offered by USEPA is not the result of a lawfully conducted notice and comment rulemaking process, nor does it cite any specific portion of any rule or statute with which the SSM rules are inconsistent. The substantive rights

of the regulated community are affected by the enforcement discretion interpretation contained in the Bennett memoranda. Therefore, rulemaking is required in order for the interpretation contained in the policy memoranda to be enforceable.

Response: Policy documents generally interpret the statute and do not establish binding requirements. Therefore, they are not subject to notice and comment rulemaking. As discussed above, rulemaking such as this provides the public with an opportunity to comment and to question USEPA's policy interpretations. If a sufficient basis had been provided for USEPA to revise or deviate from its policy, the Agency would do so. However, the comments submitted have not persuaded the Agency to change the existing policy, nor its application with respect to the Michigan SSM rule.

Comment: The enforcement discretion approach is insufficient following recent statutory and program changes. Title V of the CAA requires that the Responsible Official certify, under penalty of imprisonment, all data as truthful, accurate, and complete and requires periodic submittal of certifications by the Responsible Official detailing the compliance status of each facility. Thus, the Responsible Official for each Title V source has a duty to disclose any noncompliance with any applicable regulation. In addition, the 1990 Amendments provided enhanced criminal penalty provisions and revised the citizen suit provisions, increasing the likelihood of CAA enforcement actions. If an owner or operator of a source has knowledge that a process during startup or shutdown would possibly violate an emission limitation and proceeds to startup or shutdown the process, that knowledge could satisfy the intent requirement for a criminal prosecution. In many cases, compliance with applicable regulations during startup, shutdown, or malfunctions is technically or economically impossible. The SSM regulations contained in Michigan's SIP provide owners and operators of facilities with the appropriate protection against prosecution for startup problems of older facilities.

The enforcement discretion approach asks the regulated industry to rely on the exercise of discretion by both state and federal agencies. In addition, if such dual discretion does occur, nothing prevents citizens from pursuing a civil action to impose penalties on the source for the emission violations. Because of the enhanced federal and state statutes, the creation of criminal liability, and the lack of protection from citizen suits, a reliance on enforcement discretion is insufficient.

Response: With respect to start-up and shutdown situations, it is USEPA's general policy, as set forth in the Bennett memoranda, that: ''Startup and shutdown of process equipment are part of the normal operation of a source and should be accounted for in the planning, design and implementation of operating procedures for the process and control equipment. Accordingly, it is reasonable to expect that careful and prudent planning and design will eliminate violations of emission limitations during such periods.'' If there are circumstances where a source cannot comply with the SIP during start-up, shutdown or maintenance situations despite careful and prudent planning and design, the State should address these particular problems in development of (or revision to) the underlying rules applicable to those sources and not through overarching excess emissions provisions. (Any revision made to the state's rules to address these concerns must be submitted to USEPA as a SIP revision request.)

USEPA is cognizant of the various remedies under the Clean Air Act for SIP violations, including those available under the criminal suit provisions of Section 113(c). It should be noted, however, that no criminal action may be brought under that section unless a person knowingly violates the applicable requirement ''* * * more than 30 days after having been notified * * * that such person is violating such requirement or prohibition* * *.'' Thus, the scenario envisioned by the commentor is not realistic, unless appropriate notice is given and the violations continue. As discussed earlier, where there is such a likelihood of continuing violation, sources should seek relief through the SIP revision process.

USEPA also believes that the commentor's concern about the perceived inadequacy of an enforcement discretion approach is misplaced. The CAA has long provided for enforcement of SIP violations. Moreover, the revisions to enforcement provisions in 1990 were not intended to impact substantive regulations. Rather they were included with the recognition that the CAA has, at times, been difficult to enforce. USEPA further notes that reliance on the judicial system and courts' equitable discretion provides further protection.

Comment: Michigan's SSM provisions are consistent with the February 15, 1983 memorandum from Kathleen M. Bennett, Assistant Administrator for Air, Noise and Radiation to the Regional Administrators entitled ''Policy on Excess Emissions During Startup, Shutdown, Maintenance and Malfunctions.'' The SSM rules contain all of the criteria required to be considered by the regulator in determining whether enforcement action or discretion is warranted.

Response: The criteria referenced above are to be considered when determining whether to exercise enforcement discretion for periods of excess emissions caused by a malfunction, not to excuse those emissions. As discussed previously, because SIPs protect ambient-based standards, any emissions above the allowable may cause or contribute to violations of the NAAQS, and therefore cannot be excused. State and federal agencies (and citizens) need to be able to seek relief where public health may be threatened by periods of excess emissions.

Furthermore, the criteria referenced above apply only in the case of malfunctions. They do not apply to periods of excess emissions caused by startup, shutdown or maintenance (unless the excess is attributable to a malfunction occurring during those times). Start-up and shutdown of process equipment are part of the normal operation of a source and should be accounted for in the design and implementation of the operating procedure for the process and control equipment. Accordingly, it is reasonable to expect that, in most cases, careful planning will eliminate violations of emission limitations during such periods.

Moreover, even if USEPA did determine that the state could excuse these emissions, there remain issues which make the rules unapprovable. The definitions of ''malfunction,'' contained in 324.5509(1), part 55 of the Michigan Natural Resources and Environmental Protection Act and R 336.1113(d), Michigan administrative code, do not limit malfunctions to failures that are ''infrequent'' and ''not reasonably preventable,'' and are therefore too broad. [See e.g. 40 CFR 60.2] Frequent or reasonably preventable excess emissions would tend to indicate an underlying problem with the design, operating procedures or maintenance of a source and therefore should not be considered a malfunction. The State's bypass provisions in SIP R 336.1913(3)(b) and R 336.1914(4)(b) are also too broad. USEPA policy regarding bypass states that ''* * * if effluent gasses are bypassed which cause an emission limitation to be exceeded, this excess need not be treated as a violation

if the source can show that the excesses could not have been prevented through careful and prudent planning and design and that bypassing was unavoidable to prevent loss of life, personal injury or severe property damage.'' [Memorandum dated February 15, 1983, from Kathleen M. Bennett, Assistant Administrator for Air, Noise and Radiation entitled ''Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions'']. The USEPA continues to believe that this is a necessary policy, and that the bypass provisions contained in the State's rule are inadequate for the reasons stated in that policy.

In addition, the alternate emission limitations for startups and shutdowns in R 336.1914(4)(d) could (impermissibly) allow relaxations of Act requirements, including NSR limitations, New Source Performance Standards, toxics requirements (NESHAP, MACT), etc. Finally, the State SSM regulations provide no authority for MDEQ to review and require revisions to a source's written emission minimization plan for normal or usual startups and shutdowns. Such authority is necessary to ensure that operating practices for startups and shutdowns meet good engineering practice for minimizing emissions, similar to the authority R 336.1911 currently provides for State review and revision of written preventative maintenance and malfunction abatement plans.

Comment: The USEPA's position is not consistent with existing, long-standing regulations, and not consistent with its own rulemakings in other state's SIPs. Unless the USEPA intends to rescind 40 CFR 63 and other state SIPS as being inconsistent with the CAA, and then propose a general rule consistent with its internal memoranda, the USEPA's argument that Michigan's SSM rules do not comply with the CAA is without merit.

Response: As previously discussed, the difference in approach between the technology-based NESHAP rules and air quality-based SIP rules merits the different treatment for provisions concerning SSM excess emissions. With regard to the suggestion that USEPA's action on the Michigan submission is somehow inconsistent with its action(s) with other state submission, without additional information on which state(s) the commentor is referencing, USEPA cannot reasonably respond to this comment. However, as noted previously, USEPA continues to support the policy established by the Bennett memoranda for the reasons stated in those memoranda and in this rulemaking action. It should nonetheless be noted that, even if the commentor had identified such an inconsistent action, USEPA would not be precluded from disapproving Michigan's SSM submission. *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 121 F. 3d 106 (3d Cir. 1997).

Comment: The USEPA does not identify any deficiencies with Rule 912. Therefore, Rule 912 should be approved as part of the SIP.

Response: USEPA acknowledges that it did not cite any deficiencies for Rule 912 in its notice of proposed rulemaking. However, USEPA believes that when Rule 912 was adopted by Michigan, it was promulgated as an integral part of the SSM regulations; i.e., the protection granted in Rules 913 and 914 is contingent on meeting the operating, notification and reporting requirements in Rule 912. In this case, approving Rule 912 while disapproving Rules 913 and 914 would result in establishing operating, notification and reporting requirements for sources without granting the protection to them contemplated by the companion rules. Under existing case law, USEPA may not partially approve a state SIP submission if such action will result in the approved rules being more stringent than was intended by the state when they were adopted. See *Bethlehem Steel Corp*. v. *Gorsuch,* 742 F. 2d 1028 (7th Cor. 1984); *Indiana and Michigan Elec. Co.* v. *U.S.E.P.A.,* 733 F. 2d 489 (7th Cir. 1984).

III. Final Rulemaking Action

To determine the approvability of a rule, USEPA must evaluate the rule for consistency with the requirements of the Act, USEPA regulations and the USEPA's interpretation of these requirements as expressed in USEPA policy guidance documents. While USEPA understands the concerns raised by the commentors, rules 913 and 914 remain inconsistent with the Act and the applicable policies by which USEPA must evaluate submittals. Therefore, in today's action, USEPA is finalizing the disapproval proposed on March 20, 1997.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. The EPA shall consider each request for revision to the SIP in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. § 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. §§ 603 and 604). Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

USEPA's disapproval of the State request under Section 110 and subchapter I, part D of the Clean Air Act does not affect any existing requirements applicable to small entities. Any pre-existing Federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect its state enforceability. Moreover, USEPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, USEPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements and impose any new Federal requirements.

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the disapproval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal disapproval action imposes no new requirements. Accordingly, no additional costs to

State, local, or tribal governments, or to the private sector, result. No new Federal requirements are imposed. Accordingly, no additional costs to state, local, or tribal governments, or the private sector, result from this action.

D. Small Business Regulatory Enforcement Fairness Act

The Congressional Review Act, 5 U.S.C. § 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. USEPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 21, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

V. List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. § 7401 *et seq.*

Dated: January 30, 1998.

David A. Ullrich,

Acting Regional Administrator, Region V.

[FR Doc. 98–4003 Filed 2–19–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 157

[OPP–250125; FRL–5764–3]

Termite Insecticide Bait Stations; Exemption From Adult Portion of Child-Resistant Testing Specifications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Exemption Order.

SUMMARY: This Order grants a 5–year exemption from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2) (Ease of adult opening), for prefilled, nonrefillable termite insecticide bait stations not designed or intended to be opened or activated in a manner that exposes the contents to human contact. Products qualifying for this exemption must still fully comply with all other child-resistant packaging (CRP) effectiveness, compatibility, and durability standards, as well as all other requirements of 40 CFR part 157. CRP certification for products relying on this exemption must specify that the package does not comply with the senior and younger adult effectiveness specifications per this exemption. This exemption was requested by Griffin Corporation and FMC APG Specialty Products, who suggested that a package that does not require opening or activation to put into use should not require adult ease of opening testing.

DATES: This exemption Order becomes effective on February 20, 1998 and expires on February 20, 2003.

FOR FURTHER INFORMATION CONTACT: Rosalind L. Gross, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone number: (703) 308–7368, e-mail: gross.rosalind@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Griffin Corporation and FMC APG Specialty Products requested an exemption from the senior-adult test and younger-adult test effectiveness specifications, described in 16 CFR 1700.15(b)(2) (Ease of adult opening), for prefilled, nonrefillable termite insecticide bait stations that are not designed or intended to be opened or activated in a manner that exposes the contents to human contact.

I. Background

FIFRA 25(c)(3) requires EPA's CRP standards to be consistent with those of the Consumer Product Safety Commission (CPSC). EPA's CRP regulations at 40 CFR 157.32 require that CRP for pesticides meet the CPSC packaging standards (effectiveness specifications) and testing procedures set forth in 16 CFR 1700.15(b) and 1700.20. The CPSC Poison Prevention Packaging Standards in 16 CFR 1700.15(b) provide that CRP, when tested by the method described in 16 CFR 1700.20, shall meet certain child-resistant test, senior-adult test, and younger-adult test effectiveness specifications. In 16 CFR 1700.15(b)(2), the senior-adult test and younger-adult test effectiveness specifications are discussed with reference to the senior-adult panel test of 16 CFR 1700.20(a)(3) and the younger-adult panel test of 16 CFR 1700.20(a)(4), respectively.

The EPA CRP regulations provide that exemptions from compliance may be requested on a case-by-case basis for specific products based on technical factors (40 CFR 157.24(b)(3)). The regulations further provide that any such exemption decision will be published in the **Federal Register**, will be for a specified length of time, and will be applicable to any product with substantially similar composition and intended uses.

II. Requested Grounds for Exemption

As support for the exemption request, Griffin Corporation and FMC APG Specialty Products advanced the following arguments:

The purpose of adult testing is to ensure that the package is not difficult for adults to use properly. If CRP is difficult for adults to open, the concern arises that the package may be disabled or left unsecured to eliminate the difficulty of reopening it. Under such circumstances the contents would be accessible to children. In the case of prefilled, nonrefillable termite insecticide bait stations not designed or intended to be opened, this concern does not arise. There is no risk that an adult will disable or fail to resecure a difficult to open package, because the packages need not be opened or activated in order to function properly. As there is no concern that an adult will disable or fail to resecure such a package, there is also no concern that the contents of disabled or unsecured packages will be accessible to children. Instead, from a child safety standpoint, the only relevant question regarding such packages is whether they can prevent a child from gaining access to the bait.

III. Agency Determination

The Agency has considered the Griffin Corporation and FMC APG Specialty Products exemption request