§ 52.222 Negative declarations.

(a) * * * (6) * * *


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(b) * * * (4) * * *


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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301043; FRL–6740–9]

RIN 2070–AB78

Sodium o-nitophenolate, sodium p-nitophenolate, sodium 5-nitroguaiacolate, and the End–Use Product Atonik® Exemption From the Requirement of a Tolerance and Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the active ingredients (a.i.) sodium o-nitophenolate, sodium p-nitrophenolate, sodium 5-nitroguaiacolate, on all food commodities when used as Plant Growth Regulators on growing crops. These three a.i. comprise the end-use ingredients (a.i.) sodium 5-nitroguaiacolate, on all food commodities when used as Plant Growth Regulators on growing crops.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select “Laws and Regulations,” “Regulations and Proposed Rules,” and then look up the entry for this document under the “Federal Register—Environmental Documents.” You can also go directly to the Federal Register listings at http://www.epa.gov/fedregstr/.

2. In person. The Agency has established an official record for this action under docket control number OPP–301043. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents.

The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the Federal Register of July 8, 1998 (63 FR 36901) (FRL–5791–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide tolerance petition by ASAHI Manufacturing Company, Ltd., c/o Chemical Consultants International, Inc., West 98th Terrace, Suite 100, Overland Park, KS, 66212. This notice included a summary of the petition prepared by the petitioner ASAHI Manufacturing Company, Ltd. There were no comments received in response to the notice of filing.

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in...
residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...” Additionally, section 408(b)(2)(D) requires that the Agency consider “available information concerning the cumulative effects of a particular pesticide’s residues” and “other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The Biopesticide and Pollution Prevention Division (BPPD) has reviewed submitted data to assess the potential hazards and exposures that might result from the proposed use of ATONIK® in or on all food commodities. The plant growth regulator will be formulated into an end-use product containing a mixture of 0.6% a.i. sodium 5-nitroguaiacolate (1%), sodium o-nitrophenolate (0.2%), and sodium p-nitrophenolate (0.3%) by weight and applied to all crops at rates of less than 20 grams a.i. (g a.i.) per acre. Based on the review of submitted information, dose levels and toxicity end-points were evaluated for the use of exposure estimates to characterize potential risks.

The Tier I data was submitted on the end-use product, ATONIK®, each of the three a.i., sodium o-nitrophenolate, sodium p-nitrophenolate, sodium 5-nitroguaiacolate, and a manufacturing use product (a mixture of the components). No toxicity endpoints for dietary occupational or non-occupational risk characterizations were indicated because:

1. The no-observed-adverse-effect levels (NOAEL) from dietary administration of the a.i. are 5–6 times higher than that of the developmental toxicity study (1,589 and 1,723 milligrams/kilograms/day (mg/kg/day) for males and females compared with 300 mg/kg/day in pregnant rats).
2. The acute toxicity of the end-use product is classified into Toxicity Category IV for the oral (LD₅₀ > 5,000 mg/kg) and inhalation LC₅₀ > 5.8 mg/L routes and Toxicity Category III for the dermal route (LD₅₀ > 2,000 mg/kg).
3. No developmental effects were noted at dose up to 600 mg/kg/day highest dose tested (HDT).
4. Studies on the three components of the manufacturing use product (MUP) showed no mutagenic activity.
5. The low concentration of the a.i. in the end use product (0.6%).
6. There is a low application rate (< 20 g a.i. per acre).

### IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non–occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

#### A. Dietary Exposure

No toxicity endpoints for dietary, occupational or non–occupational risk characterizations were indicated in subchronic toxicity, developmental toxicity or mutagenicity studies on ATONIK® or its three a.i.. The application rate is so low (< 20 g a.i/acre) that negligible or non-existent residues would be available for risk characterization. Therefore, considering the lack of toxicity and low exposure no risk characterizations have been conducted for ATONIK®.

#### 1. Food

The end-use product, ATONIK®, contains three a.i. (sodium 5-nitroguaiacolate, sodium o-nitrophenolate, and sodium p-nitrophenolate) in very low concentrations. At the application rates employed, the level of each a.i. which may be present in any of the food or feed items would be far below the levels which demonstrated any effects in the subchronic oral feeding study, the developmental toxicity study or the mutagenicity studies. It can be shown that in order to reach a dose rate comparable to the LOAEL of 1,600 mg/kg/day obtained in the subchronic oral feeding study, a person weighing 50 kg (100 lbs.) would have to consume all of the produce from 4 acres of crop every day.

Further, due to the rapid uptake and metabolism of the three a.i. in plants, it is unlikely that any of the residue would be available for potential exposure.

#### 2. Drinking water exposure

Similarly, exposure to humans from consumption of water would be equally unlikely.

#### B. Other Non-Occupational Exposure

Using the previously mentioned criteria, the Agency believes that non–occupational exposures via other routes would be highly unlikely. There is no allowed use of the product containing the three a.i. on lawns, rights-of-way, golf courses, or other areas where human exposure is likely to occur. Therefore, for all practical purposes, exposure from these areas would be non–existent.

### V. Cumulative Effects

Exposure through other pesticides and substances with the same mode of toxicity is not likely. What little toxicity that was observed is only detected at extremely high concentrations of these a.i.

### VI. Determination of Safety for U.S. Population, Infants and Children

The three a.i. in the End–Use Product, ATONIK®, are all classified as biochemicals. The low toxicity of each of these alone and in combination, as discussed above, demonstrates that these chemicals, at the rates established, will not pose any known risk to human health, either as children or as adults. These three a.i. are already exempted from the requirement of a tolerance for use on cotton, rice, and soybeans.

### VII. Other Considerations

#### A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the program include evaluations of potential effects in wildlife.
pesticide chemicals, EPA will use 
FIFRA and, to the extent that effects in 
wildlife may help determine whether a 
substance may have an effect in 
humans, FFDCA authority to require the 
wildlife evaluations. As the science 
develops and resources allow, screening 
of additional hormone systems may be 
added to the Endocrine Disruptor 
Screening Program (EDSP).

When the appropriate screening and/or 
testing protocols being considered 
under the EDSP have been developed, 
sodium o-nitrophenolate, sodium p-
nitrophenolate, and sodium 5-
nitoguaiacolate, may be subjected to 
additional screening and/or testing to 
better characterize effects related to 
endocrine disruption. Based on the 
weight of the evidence of available data, 
no endocrine system–related effect have 
been identified.

B. Analytical Method(s)

Adequate data for the end-use 
product, ATONIK®, and each of the 
three components: sodium o-
nitrophenolate, sodium p-
nitrophenolate, and sodium 5-
nitoguaiacolate, were submitted with 
the initial registration and petition for 
tolerances.

C. Tolerance Reassessment

The foregoing is a reassessment of the 
tolerances for § 180.1139 Sodium 5-
nitoguaiacolate, and § 180.1140 Sodium 
o-nitrophenolate, and § 180.1141 
Sodium p-nitrophenolate. This 
reassessment revises these tolerances to 
include all food commodities when 
used as plant growth regulators.

D. Codex Maximum Residue Level

No known international tolerances 
have been granted for this pesticide. 
Therefore, based on the completeness 
and reliability of the toxicity data from 
the published literature and 
conservative exposure assessment, the 
Agency concludes that there is a 
reasonable certainty that no harm will 
result from aggregate exposure to 
residues of ATONIK® including all 
anticipated dietary exposure and all 
non–occupational exposures.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as 
amended by the FQPA, any person may 
file an objection to any aspect of this 
regulation and may also request a 
hearing on those objections. The EPA 
procedural regulations which govern the 
submission of objections and requests 
Although the procedures in those 
regulations require some modification to 
reflect the amendments made to the 
FFDCA by the FQPA of 1996, EPA will 
continue to use those procedures, with 
appropriate adjustments, until the 
necessary modifications can be made. 
The new section 408(g) provides 
especially the same process for persons to 
“object” to a regulation for an 
exemption from the requirement of a 
tolerance issued by EPA under new 
section 408(d), as was provided in the 
old FFDCA sections 408 and 409. 
However, the period for filing objections 
is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an 
Objection or Request a Hearing?

You must file your objection or 
request a hearing on this regulation in 
accordance with the instructions 
provided in this unit and in 40 CFR part 
178. To ensure proper receipt by EPA, 
you must identify docket control 
number OPP–301043 in the subject line 
on the first page of your submission. All 
requests must be in writing, and must be 
mailed or delivered to the Hearing Clerk 
on or before January 2, 2001.

1. Filing the request. Your objection 
must specify the specific provisions in 
the regulation that you object to, and 
the grounds for the objections (40 CFR 
178.25). If a hearing is requested, the 
objections must include a statement of 
the factual issues(s) on which a hearing 
is requested, the objector’s contentions 
on such issues, and a summary of any 
evidence relied upon by the objector (40 
CFR 178.27). Information submitted in 
connection with an objection or hearing 
request may be claimed confidential by 
marking any part or all of that 
information as CBI. Information so 
marked will not be disclosed except in 
accordance with procedures set forth in 
40 CFR part 2. A copy of the 
information that does not contain CBI 
must be submitted for inclusion in the 
public record. Information not marked 
confidential may be disclosed publicly 
by EPA without prior notice.

Mail your written request to: Office of 
the Hearing Clerk (1900), Environmental 
Protection Agency, 1200 Pennsylvania 
Ave., NW., Washington, DC 20460. 
You may also deliver your request to 
the Office of the Hearing Clerk in Rm. 
C400, Waterside Mall, 401 M St., SW., 
Washington, DC 20460. The Office 
of the Hearing Clerk is open from 8 a.m. 
to 4 p.m., Monday through Friday, 
excluding legal holidays. The telephone 
number for the Office of the Hearing 
Clerk is (202) 260–4865.

2. Tolerance fee payment. If you file 
an objection or request a hearing, you 
must also pay the fee prescribed by 40 
CFR part 178 for filing objections or 
that fee pursuant to 40 CFR 180.33(m). You 
must mail the fee to: EPA Headquarters 
Accounting Operations Branch, Office of 
Pesticide Programs, P.O. Box 
360277M, Pittsburgh, PA 15251. Please 
identify the fee submission by labeling 
it “Tolerance Petition Fees.”

EPA is authorized to waive any fee 
requirement “when in the judgement of 
the Administrator such a waiver or 
refund is equitable and not contrary to 
the purpose of this subsection.” For 
additional information regarding the 
waiver of these fees, you may contact 
James Tompkins by phone at (703) 305– 
5697, by e-mail at 
tompkins.jim@epa.gov, or by mailing a 
request for information to Mr. Tompkins 
at Registration Division (7505C), Office of 
Pesticide Programs, Environmental 
Protection Agency, 1200 Pennsylvania 
Ave., NW., Washington, DC 20460.

If you would like to request a waiver 
of the tolerance objection fees, you must 
mail your request for such a waiver to: 
James Hollins, Information Resources 
and Services Division (7502C), Office of 
Pesticide Programs, Environmental 
Protection Agency, 1200 Pennsylvania 
Ave., NW., Washington, DC 20460.

3. Copies of the docket. In addition 
to filing an objection or hearing request with the Hearing Clerk as described in 
Unit VIII.A., you should also send a 
copy of your request to the PIRIB for its 
inclusion in the official record that is 
described in Unit I.B.2. Mail your 
copies, identified by docket control 
number OPP–301043, to: Public 
Information and Records Integrity 
Branch, Information Resources and 
Services Division (7502C), Office of 
Pesticide Programs, Environmental 
Protection Agency, 1200 Pennsylvania 
Ave., NW., Washington, DC 20460. 
In person or by courier, bring a copy to 
the location of the PIRIB described in 
Unit I.B.2. You may also send an electronic 
copy of your request via e-mail to: opp-
docket@epa.gov. Please use an ASCII 
file format and avoid the use of special 
characters and any form of encryption. 
Copies of electronic objections and 
hearing requests will also be accepted on 
disks in WordPerfect 6.1/6.0 file 
format or ASCII file format. Do not 
include any CBI in your electronic copy. 
You may also submit an electronic copy 
of your request at many Federal 
Depositary Libraries.

B. When Will the Agency Grant a 
Request for a Hearing?

A request for a hearing will be granted 
if the Administrator determines that the 
material submitted shows the following: 
There is a genuine and substantial issue 
of fact; there is a reasonable possibility 
that material evidence exists. A request for 
a hearing, such request must be 
accompanied by a proposed order that 
would determine the outcome 
required by the requester. If the 
Administrator grants the request for 
a hearing, a hearing notice will be 
published in the Federal Register.
IX. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” October 4, 1993 (58 FR 51735). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled “Consultation and Coordination with Indian Tribal Governments” May 19, 1999 (63 FR 27655); special considerations as required by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” February 16, 1994 (59 FR 7629); or require OMB review or any Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” April 23, 1997 (62 FR 19885). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d)(15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” August 10, 1999 (64 FR 43255). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

X. Submission to Congress and the Comptroller General

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. EPA 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 this final rule in the Federal Register. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 6, 2000.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:
Authority: 21 U.S.C. 321(q), 346(a) and 374.
2. In subpart D, §180.1139, 180.1140, and 180.1141 are revised to read as follows:

§ 180.1139 Sodium 5-nitroguaiacolate; exemption from the requirements of a tolerance.

The biochemical sodium 5-nitroguaiacolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end-use products at a concentration of 0.1% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

§ 180.1140 Sodium p-nitrophenolate; exemption from the requirement of a tolerance.

The biochemical sodium p-nitrophenolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end-use products at a concentration of 0.2% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

§ 180.1141 Sodium p-nitroguiacolate; exemption from the requirements of a tolerance.

The biochemical sodium p-nitroguiacolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end-use products at a concentration of 0.3% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

[Docket No. FEMA-D-7503]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (1% annual chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[FR Doc. 00–28277 Filed 11–2–00; 8:45 am] BILLSING CODE 6560–50–S