

Commodity	Parts per million
Cucumber	0.10
Melon subgroup 9A	0.10
Okra	0.20
Vegetable, fruiting, group 8	0.20

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[FR Doc. E9-17942 Filed 7-28-09; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0189; FRL-8427-3]

S-Abscisic Acid; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the biochemical pesticide *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid in or on leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples when applied/used as a plant regulator in accordance with the terms of Experimental Use Permit (EUP) 73049-EUP-7. Valent BioSciences Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid for the uses permitted under EUP 73049-EUP-7. The temporary tolerance exemption expires on August 7, 2012.

DATES: This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0189. All documents in the docket are listed in the docket index

available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0031; e-mail address: pfeifer.chris@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to

assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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 for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0189 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 September 28, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2009-0189, by one of the following methods.

• *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of April 8, 2009 (74 FR 15969) (FRL-8407-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9G7532) by Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid in or on leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples. This notice included a summary of the petition prepared by the petitioner, Valent BioSciences Corporation, which is included in the docket for this rule. In that summary, Valent BioSciences Corporation requested an expansion of the temporary exemption of a requirement for tolerance for *S*-Abscisic Acid (commonly abbreviated as ABA) to extend to leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples pursuant to the issuance of EPA EUP Number 73049-EUP-7. This EUP is designed to test ABA for its ability to aid in fruit thinning, growth control, crop stress reduction and crop quality improvement, and proposes a maximum rate of 2,000 parts per million (ppm) per acre to be applied up to four times annually. The EUP proposes to study ABA over 3 years (until August 7, 2012) and would cover a sum total of 6,913 acres. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of 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) of FFDCA 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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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) of FFDCA 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 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.

S-Abscisic Acid is a plant regulator present in all vascular plants, algae and some fungi. Its name derives from its purported role in abscission - the shedding of leaves, fruits, flowers and seeds. As a plant hormone, *S*-Abscisic Acid is known to be a strong actor in regulating plant growth by aiding in stress resistance, fruit set, ripening, and senescence. It is naturally present in fruits and vegetables at various levels,

generally not in excess of 10 ppm, and has always been a component of any diet containing plant materials. To date, no toxic effects to humans have been associated with the consumption of ABA in fruits and vegetables.

S-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid is virtually non-toxic with regard to acute toxicity. The lethal dose (LD)₅₀ for acute oral toxicity using the rat was greater than 5,000 milligrams/kilogram (mg/kg) of body weight in female rats, so it is classified as a Toxicity Category IV for acute oral toxicity. The LD₅₀ for acute dermal toxicity using the rat was greater than 5,000 mg/kg body weight in male and female rats, so it is classified as a Toxicity Category IV for acute dermal toxicity. The lethal concentration (LC)₅₀ for acute inhalation toxicity was greater than 2.06 mg/liter (L) in male and female rats, so it is classified as a Toxicity Category IV for acute inhalation toxicity. Primary eye irritation, tested in rabbits, showed mild irritation to the eye (Toxicity Category III). Iritis and conjunctivitis cleared after 24 hours. Primary skin irritation, tested in the rabbit, showed this material to be slightly irritating. This irritation cleared within 24 hours after treatment. ABA was tested for Sensitization in the Guinea Pig and found not to be a skin sensitizer.

1. *Genotoxicity.* Three mutagenicity studies (an Ames test, a mouse micronucleus assay, and an unscheduled DNA synthesis assay in the rat) determined that ABA was not mutagenic.

2. *Developmental toxicity and Subchronic toxicity.* The Agency does not believe that there is any development toxicity or subchronic toxicity concern associated with ABA for several reasons. Public literature indicates that there are no grounds for concern with regard to the developmental toxicity or subchronic toxicity of ABA. Because of the extremely short half-life and dissipation qualities of ABA, the Agency expects treated food to return to background levels within 5 days of application; therefore, there is a lack of potential oral exposure. Moreover, ABA is virtually non-toxic through the oral route of exposure. Finally, because of the pre-existing ubiquity of ABA in our diet without issue, developmental toxicity and subchronic toxicity are not considered to be of concern.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of 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

ABA is a plant regulator present in all vascular plants, algae and some fungi. It is naturally present in fruits and vegetables at various levels, generally not in excess of 10 ppm, and has always been a component of any diet containing plant materials. Because of the rapid degradation of ABA, the proposed uses of this product are not expected to result in dietary residues in or on leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples, above the natural background levels.

1. *Food.* Residues of ABA applied to leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples can be expected to rapidly dissipate to levels consistent with those observed naturally. Data submitted by the registrant confirm ABA's dissipation through rapid metabolism, photo-isomerization, and rapid degradation. Because of its ability to dissipate rapidly, ABA, when used in accordance with the terms of EUP 73049–EUP–7, is not expected to result in residues in or on leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples, above the natural background levels typically found in other commonly consumed fruits or vegetables. As mentioned above, it is noted that ABA is already commonly consumed. It is naturally present in fruits and vegetables at various levels (up to 10 ppm) and has always been a component of any diet containing plant materials.

2. *Drinking water exposure.* Pursuant to the terms of EUP 73049–EUP–7, applications are expected to be made to leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples using a maximum application rate of 2,000 ppm per acre (using a maximum of 200 gallons). Due to the low concentration and volume of application solution, leaching into groundwater is unlikely. Applications are made directly to leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples; therefore, accidental application to lakes or streams is unlikely. However, even if ABA leached into groundwater, data show that ABA is rapidly metabolized and photo-isomerized, further diminishing the likelihood of any extra-normal ABA

residues being transferred to water. Data submitted to the Agency show ABA is also naturally present in water. The Agency therefore concludes that any residues resulting from the application of ABA to leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples are not expected to result in any significant drinking water exposure beyond natural background levels of ABA already present in water.

B. Other Non-Occupational Exposure

Potential non-occupational exposure is considered unlikely for this distinctly agricultural use pattern.

1. *Dermal exposure.* Non-occupational dermal exposures to ABA when used as a pesticide are expected to be negligible because it is limited to an agricultural use under this EUP.

2. *Inhalation exposure.* Non-occupational inhalation exposures to ABA when used as a pesticide are expected to be negligible because it is limited to an agricultural use under this EUP.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires the Agency, when considering whether to establish, modify, or revoke a tolerance, to consider “available information” concerning the cumulative effects of pesticide residues and “other substances that have a common mechanism of toxicity.” These considerations include the cumulative effects of such residues on infants and children. Because there is no indication of mammalian toxicity from ABA, the Agency concludes that ABA does not share a common mechanism of toxicity with other substances. Therefore, section 408(b)(2)(D)(v) does not apply.

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

1. *U.S. population.* The Agency has determined that there is a reasonable certainty that no harm will result from aggregate exposure to residues of ABA to the U.S. population. This includes all anticipated dietary exposures and other non-occupational exposures for which there is reliable information. The Agency arrived at this conclusion based on the relatively low levels of mammalian dietary toxicity associated with ABA, the natural ubiquity of ABA in our foodstuffs, and data indicating that the pesticidal use of ABA results in residues that approximate natural background levels. For these reasons, the Agency has determined that ABA residues on leafy vegetables, herbs and spices, pome fruit, stone fruit, grapes and pineapples will be safe, i.e., there is a reasonable certainty that no harm

will result from aggregate exposure to residues of ABA when used in accordance with the terms of EUP 73049–EUP–7.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless the EPA determines that a different margin of exposure (safety) will be safe for infants and children. Based on all the reliable available information the Agency reviewed on ABA, the Agency concludes that there are no residual uncertainties for prenatal/postnatal toxicity resulting from ABA and that ABA has relatively low toxicity to mammals from a dietary standpoint, including infants and children. Accordingly, there are no threshold effects of concern and an additional margin of safety is not necessary to protect infants and children.

VII. Other Considerations

A. Endocrine Disruptors

Based on available data, no endocrine system-related effects have been identified with the consumption of *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid.

B. Analytical Method(s)

Through this action, the Agency proposes a temporary exemption from the requirement of a tolerance of ABA when used on leafy vegetables, herbs and spices, pome fruit, stone fruit, and pineapples without any numerical limitations for residues. It has determined that residues resulting from the pesticidal uses of *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid, would be so low as to be indistinguishable from natural background levels. As a result, the Agency has concluded that an analytical method is not required for enforcement purposes for this use of ABA.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels established for residues of *S*-Abscisic Acid, (*S*)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid.

VIII. Statutory and Executive Order Reviews

This final rule establishes a temporary exemption from the requirement of a tolerance under section 408(d) of

FFDCA 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* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: July 20, 2009.

W. Michael McDavid,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ 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), 346a and 371.

■ 2. Section 180.1281 is revised to read as follows:

§ 180.1281 S-Absciscic Acid; Temporary Exemption From the Requirement of a Tolerance.

(a) *S*-Absciscic Acid, (S)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid is temporarily exempt from the requirement of a tolerance when used as a plant regulator in or on grape in accordance with the Experimental Use Permit 73049-EUP-4. This temporary exemption from tolerance will expire October 1, 2010.

(b) A temporary exemption from the requirement of a tolerance is established for the residues of *S*-Absciscic Acid, (S)-5-(1-hydroxy-2,6,6-trimethyl-4-oxo-1-cyclohex-2-enyl)-3-methyl-penta-(2*Z*,4*E*)-dienoic Acid when used as a plant regulator in or on grape, herbs and spices, leafy vegetables, pineapple,

pome fruit, and stone fruit in accordance with the Experimental Use Permit 73049-EUP-7. This temporary exemption from tolerance will expire August 7, 2012.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0477; FRL-8422-2]

Dichlormid; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for residues of dichlormid in or on field corn (forage, grain, stover); pop corn (grain, stover); and sweet corn (forage, kernel plus cob with husks removed, stover). DowAgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The time-limited tolerances expired on December 31, 2008.

DATES: This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-0477. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket