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IX. Statutory and Executive Order Reviews

This final rule establishes an 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 from the requirement of a tolerance 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 6, 2000) do not apply to this rule. In addition, this 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).

X. 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: August 1, 2007.

Debra Edwards,

Director, 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 180.1279 is added to subpart D to read as follows:

§ 180.1279 Zucchini yellow mosaic virus - weak strain; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the ZYMV-WK strain in or on all raw cucurbits when applied/used in accordance with label directions.

[FR Doc. E7–16057 Filed 8–14–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0220; FRL–8122–3]

Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CAS Reg. No. 51229–78–8); 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 cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CAS Reg. No. 51229–78–8) under 40 CFR 180.920 (growing crops) when used as an inert ingredient as a preservative at 0.14% by weight (wt) or less of pesticide formulations. Dow Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance.

DATES: This regulation is effective August 15, 2007. Objections and requests for hearings must be received on or before October 15, 2007, 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–2007–0220. To access the

electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either 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: Karen Angulo, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0404; e-mail address: angulo.karen@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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

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 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-2007-0220 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 October 15, 2007.

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-2007-0220, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of December 17, 2003 (67 FR 70251) (FRL-7336-4), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 3E6656) by Dow Chemical Company, Building 1803, Midland, Michigan 48674. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. That notice included a summary of the petition prepared by the petitioner. Dow Chemical Company requested the use of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride as a preservative at 0.14% by weight or less in pesticide formulations. No comments were received in response to the notice of filing.

Section 408(b)(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 tolerance is "safe." Section 408(c)(2)(A)(ii) of the 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. Section 408(b)(2)(C) of the FFDCA 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...." These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

III. Risk Characterization and Conclusion.

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 nature of the toxic effects caused by cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride are discussed in this unit. EPA has sufficient data to assess the hazards of and make a determination on aggregate exposure for the chemical. The following provides a brief summary of the risk assessment and conclusions for the Agency's review of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. The full decision document for this action is available on EPA's Electronic Docket at <http://www.regulations.gov/> under docket number EPA-HQ-OPP-2007-0220.

A. Human Health

The Agency reviewed the available information on cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride submitted by the petitioner as well as additional information available to EPA and the data evaluated in the 1995 Dowicil®CTAC RED. The toxicity database is sufficient for cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. In laboratory animal studies measuring acute toxicity, cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is slightly toxic in acute inhalation and oral toxicity studies. Dermal effects were observed in rabbits at close to the limit dose (no observed adverse effect level of 1,000 milligram/kilogram/day (mg/kg/day)) in a subchronic study, and in a dermal acute toxicity study the LD₅₀ was determined to be 923 mg/day. The chemical was mutagenic in the *in vitro* Chinese hamster ovary cell HGPRT (Hypoxanthine guanine phosphoribosyl transferase) forward mutation assay with activation, but was nonmutagenic without activation. It was negative in two other mutagenicity studies. Developmental effects were observed at or above the level of maternal toxicity (optic malformations may be linked to genetic issues rather than exposure to the chemical). Chronic toxicity studies are not available, nevertheless, sufficient information is available in sub-chronic and developmental toxicity studies.

B. Exposure Assessment

The potential for exposure to residues of cis-isomer of 1-(3-chloroallyl)-3,5,7-

triaza-1-azoniaadamantane chloride is adequately characterized based on the chemical's non-persistent nature and ready dissipation in the environment and the low use rate. Exposures from residues in food and drinking water are expected to be minimal. Residential exposure (inhalation and dermal) is also expected to be minimal from the use of the chemical in pesticides considering the low application rate. Residential exposures from non-pesticides uses are not anticipated to be of concern considering the low dermal toxicity findings. The Agency concludes dietary and residential exposures of concern are not anticipated from the inert ingredient use of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride considering its non-persistent nature in the environment, low toxicity, and the limitations imposed on its proposed use under 40 CFR 180.920 as a preservative at 0.14% by weight (wt) or less of the pesticide formulation.

C. Safety Factor for Infants and Children

Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. The toxicity database is sufficient for cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride and potential exposure is adequately characterized based on the low use rate. In terms of hazard, there are low concerns and no residual uncertainties regarding prenatal and/or postnatal toxicity.

D. Cumulative Exposure

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-

azoniaadamantane chloride and any other substances, and the chemical does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

E. Other Considerations

1. *Analytical methods.* Adequate enforcement methodology is available to enforce the tolerance exemption expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov. Residues are not expected because of the chemical's ready degradation in the environment and the low amount that will be permitted in the pesticide formulation (limited to 0.14% by weight (wt) or less).

2. *International tolerances.* The Agency is not aware of any country requiring a tolerance for cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CAS Reg. No. 51229-78-8) nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

F. Determination of Safety and Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to residues of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. Accordingly, EPA finds that exempting cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride from the requirement of a tolerance will be safe. EPA is establishing a tolerance exemption in 40 CFR 180.920 for cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride when it is used as an inert ingredient as a preservative at 0.14% by weight or less in pesticide formulations.

IV. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 tolerance 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 6, 2000) do not apply to this rule. In addition, This 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).

V. 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: August 3, 2007.

Lois Rossi,

Director, Registration 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 180.920, is amended by adding alphabetically the inert ingredient to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CAS Reg. No. 51229-78-8)	Maximum of 0.14% by weight of formulation	Preservative

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0545; FRL-8143-1]

Lambda-Cyhalothrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of lambda-cyhalothrin, 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-

(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate in or on cucurbit vegetables (Group 9), tuberous and corm vegetables (Subgroup 1C), grass (forage, fodder, and hay) (Group 17), barley, buckwheat, oat, rye, wild rice, and pistachios. Syngenta Crop Protection, Inc. and the Interregional Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 15, 2007. Objections and requests for hearings must be received on or before October 15, 2007, and must be filed in accordance with the