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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0149; FRL-7192-5]

Dichlormid; Extension of Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes time-limited tolerances for residues of the inert ingredient (herbicide safener) dichlormid (*N,N*-diallyl dichloroacetamide) in or on corn commodities (forage, grain, stover) at 0.05 ppm. Dow AgroSciences requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances expired on March 27, 2002. This rule will re-establish these tolerances and extend them to December 31, 2005.

DATES: This regulation is effective August 7, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0149, must be received on or before October 7, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0149 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva C. Alston, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8373; e-mail address: alston.treva@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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/fedrgrstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0149. 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 September 16, 1998 (63 FR 49568) (FRL-6025-8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170), announcing the filing of a pesticide petition (PP 6F03344) by Zeneca Ag Products, 1800 Concord Pike, Wilmington, DE. This notice included a summary of the petition prepared by Zeneca Ag Products, the petitioner at that time. There were no comments received in response to the notice of filing. The Agency published a final rule in the **Federal Register** on March 27, 2000 (65 FR 16143) (FRL-6498-7) establishing time-limited tolerances, expiring on March 27, 2002. In correspondence to the Agency, Zeneca requested additional time past March 2002 for data generation. On November 9, 2000, Zeneca Ag Products sold certain parts of its business to Dow AgroSciences. In connection with the sale, Zeneca Ag Products transferred all rights, title, and interest in dichlormid to Dow AgroSciences. The new petitioner, Dow AgroSciences, has similarly requested additional time for data generation. In the **Federal Register** of May 22, 2002 (67 FR 35996) (FRL-6836-4), EPA issued a notice pursuant to section 408 of the FFDCA 21 U.S.C. 346a, as amended by the FQPA of 1996 (Public Law 104-170) announcing the filing of PP 6F03344 by Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268. This notice included a summary of the petition prepared by Dow Agrosciences. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.469 be amended by establishing tolerances for residues of the herbicide safener dichlormid, in or on field corn grain, field corn forage, and field corn fodder at 0.05 part per million (ppm).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish 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(b)(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...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of dichlorimid on field corn grain; field corn forage; and field corn fodder, (now corn, field, grain; corn, field, forage; and corn, field, stover) at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

The Agency prepared a risk assessment which was used as the basis for establishing time-limited tolerances in residues of corn, field, grain; corn, field, forage; and corn, field, stover. A final rule for these tolerances was published in the **Federal Register** of March 27, 2000. Based on the risk assessment, EPA concluded at that time that all of the risks are below the Agency's level of concern and there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to residues of dichlorimid on corn commodities.

For a complete description of the toxicological profile and endpoints, the uncertainty factors, the exposure assessment which included dietary exposure for both food and drinking water, the safety factor for infants and

children, and aggregate risk for dichlorimid, see the final rule of March 27, 2000.

The final rule of March 27, 2002, discussed data gaps which needed to be addressed before permanent tolerances could be established. Data generation is underway. According to a schedule provided by Dow AgroSciences, the following studies have been completed:

1. Chronic Feeding Study-Dog
2. 2-Generation Reproduction Study-Rat
3. General Metabolism
4. Acute Neurotoxicity
5. Subchronic Neurotoxicity
6. Plant Metabolism
7. Animal Metabolism

Studies remaining to be completed are: Crop Field Trials and Rotational Crop (Confined). Upon completion of all studies, Dow Agrosciences will submit them to the Agency. The last scheduled completion date is June 2003 for the Rotational Crop (Confined) Study. Upon receipt, the Agency will review and evaluate these studies, and prepare a new risk assessment. The Agency believes that this review and evaluation, as well as the preparation of a new risk assessment will be completed by December 31, 2005. Until that time, this final rule establishes the time-limited tolerances expiring December 31, 2005 in order to allow for the completion and then subsequent Agency review and evaluation of these studies.

There are a large number of studies that remain outstanding. However, the data gaps are not as extensive as it would seem. The nature of the residue in corn was previously found to be understood based on the published metabolism studies for a structurally similar chemical. Since the Agency's understanding of the plant metabolism of dichlorimid was derived from an extrapolation from surrogate data, a plant metabolism study in accordance with OPPTS guidelines 860.1300 using dichlorimid is required.

For the crop field trials, both pre-and post-emergent data using dichlorimid have been provided. More field trials are to be submitted in order to fulfill the guideline requirements.

To account for the incomplete toxicological database, the Agency retained an additional 10X safety factor for infants and children as to acute risk and an additional 30X safety factor as to chronic risk. Once the data gaps have been fulfilled, retention of these safety factors will be evaluated.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography) is available to

enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of dichlorimid in corn commodities.

V. Conclusion

Therefore, the time-limited tolerances are re-established for residues of the inert ingredient herbicide safener, dichlorimid, *N,N*-diallyldichloracetamide in corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; and corn, pop, stover at a tolerance level of 0.05 ppm. These tolerances will expire and be revoked on December 31, 2005. These tolerances are being established on a time-limited basis due to an incomplete database. The following toxicological data gaps (OPPTS Harmonized Test Guideline) have been identified:

- Chronic Feeding Study in Dogs, Test Guidelines 870.4100.
- 2-Generation Reproductive Study in Rats, Test Guideline 870.3900.
- General Metabolism Study, Test Guideline 870.6200.
- Subchronic Neurotoxicity Study, Test Guideline 870.6200.

The following product and residue chemistry data were also identified:

- Product Chemistry Data-color, Test Guideline 830.6302; physical state, Test Guideline 830.6303; odor, 830.6304; melting point, Test Guideline 830.7200; boiling point, Test Guideline 830.7220; water solubility, Test Guideline 830.7840; and stability, Test Guideline 830.6313.

- Plant Metabolism Study, Test Guideline 860.1300.
- Animal Metabolism Studies, Test Guideline 860.1300.

- Crop Field Trials, 860.1500.
- Rotational Crop Study, Test Guideline 860.1850 (Confined Study).

The toxicological product chemistry and residue chemistry data gaps as identified must be addressed before a permanent tolerance can be established.

VI. 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 for hearings appear in 40 CFR part 178.

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 essentially 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 ID number OPP-2002-0149 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 7, 2002.

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 requestor'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 180.33(i) or request a waiver of 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 for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.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 ID number OPP-2002-0149, 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 6.1/8.0 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 Depository 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 available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance 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* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, 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). 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 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 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. 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* (64 FR 43255, August 10, 1999). 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). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. 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: July 31, 2002.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. Section 180.469 is amended by revising the table in paragraph (a) to read as follows:

§ 180.469 N,N-diallyl dichloroacetamide; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Corn, field, forage	0.05	12/31/05
Corn, field, grain	0.05	12/31/05
Corn, field, stover	0.05	12/31/05
Corn, pop, grain	0.05	12/31/05
Corn, pop, stover	0.05	12/31/05

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket 96-132; FCC 02-24]

Upper and Lower L-Band

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document establishes licensing policies governing mobile-

satellite service (“MSS”) in certain portions of the L-band. It assigns lower L-band frequencies to Motient Services, Inc. (“Motient”) in lieu of upper L-band frequencies that have been assigned to Motient, and that the United States has been unable to coordinate internationally for use by a U.S. licensee. Any coordinated lower L-band spectrum not required to secure Motient an aggregate of 20 megahertz of L-band spectrum will be made available for other MSS applicants that may wish to apply for assignment of the frequencies. This document also adopts and incorporates into part 25 of the Commission’s service rules specific operational parameters and technical requirements to ensure that the integrity of maritime distress and safety communications service will not be compromised by MSS operation in the lower L-band.

DATES: Effective September 6, 2002.

FOR FURTHER INFORMATION CONTACT:

Terrence E. Reideler, Attorney Advisor, Satellite Division, International Bureau at 202-418-2165.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s Report and Order (R&O) in IB Docket No. 96-132, FCC 02-24, adopted January 28, 2002 and released February 7, 2002. The complete text of this R&O is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW, Room CY-A257, Washington, DC 20554. This document may also be purchased from the Commission’s duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, Room CY-B402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898 or via email qualexint@aol.com. It is also available on the Commission’s website at <http://www.fcc.gov>.

1. In the Notice of Proposed Rulemaking (NPRM), FCC 96-259 published at 61 FR 40772, August 6, 1996 preceding this R&O, the Commission asked for comment on the possibility of assigning up to a maximum of 28 megahertz of internationally coordinated upper and lower L-band spectrum to Motient. Additionally, the Commission asked for comment on whether any spectrum coordinated for U.S. use above 28 megahertz should be made available to future MSS applicants. The Commission also proposed a series of technical and operational standards designed to prevent new MSS operations from interfering with maritime distress and safety communications in the lower L-band.