

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2005-0477; FRL-8866-2]

**Dichlormid; Pesticide Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of dichlormid in or on field corn, pop corn, and sweet corn commodities. Dow AgroSciences requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 23, 2011. Objections and requests for hearings must be received on or before May 23, 2011, 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 Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Pv Shah, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-1846; e-mail address: [shah.pv@epa.gov](mailto:shah.pv@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 those engaged in the following activities:

- 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 to provide 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 get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 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. 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-2005-0477 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 23, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2

may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2005-0477, 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. Summary of Petitioned-For Tolerance**

In the **Federal Register** of December 22, 2010 (75 FR 80489) (FRL-8857-8), 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 petition (PP 9E7517) by Dow AgroSciences, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing permanent tolerances for residues of the herbicide safener dichlormid, N,N-diallyl-2,2-dichloroacetamide, in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover at 0.05 parts per million (ppm). That notice referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of 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) 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. Section 408(b)(2)(C) of 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.”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 for dichlormid including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with dichlormid follows.

In the **Federal Register** of March 27, 2000 (65 FR 16143) (FRL-6498-7), EPA published a final rule establishing time-limited tolerances for residues of the herbicide safener dichlormid in or on field corn forage, grain and stover; and pop corn grain and stover at 0.05 ppm. In the **Federal Register** of September 30, 2004 (69 FR 58285) (FRL-7680-8), EPA published a final rule establishing time-limited tolerances for residues of dichlormid in or on sweet corn forage, kernel plus cob with husks removed, and stover at 0.05 ppm. EPA has extended the expiration date of the time-limited tolerances on several occasions, most recently in the **Federal Register** of July 29, 2009 (74 FR 37621) (FRL-8422-2). The tolerances expired on December 31, 2010.

The corn tolerances were time-limited due to an incomplete database for dichlormid. Data gaps included several chemistry and toxicology studies, as identified in the March 27, 2000 and September 30, 2004 final rules. In addition, in December, 2007, EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides (40 CFR part 158, subpart F), including safeners, such as dichlormid. The outstanding chemistry and toxicology data (including immunotoxicity testing) have all been submitted and reviewed, so that the database for dichlormid is now considered complete. No changes in tolerance levels or toxicological endpoints and doses used in the human health risk assessment for dichlormid are needed as a result of the new data.

Copies of EPA’s reviews of these data may be found in docket ID number EPA-HQ-OPP-2005-0477.

The risk assessments that EPA relied on in establishing and extending the time-limited tolerances for dichlormid were highly conservative. Due to the nature and number of data gaps and qualitative evidence of increased susceptibility of *in utero* rabbits in a prenatal developmental toxicity study, the FQPA safety factor (SF) was retained at 10X for the acute dietary risk assessment and increased to 30X for the chronic dietary risk assessment. Since the data gaps have been filled, uncertainty factors associated with database deficiencies may be removed. In addition, EPA used tolerance level residues, 100 percent crop treated, and default processing factors in the dietary food exposure assessments and made conservative (protective) assumptions in the modeling used to assess exposure to dichlormid in drinking water. Using these highly conservative assumptions and SFs, acute dietary exposure to dichlormid in food was estimated to be less than or equal to 7.5% of the acute population adjusted dose (aPAD) for all population subgroups; chronic dietary exposure to dichlormid in food was estimated to be less than or equal to 15% of the chronic population adjusted dose (cPAD) for all populations subgroups.

Because this prior risk assessment showed dichlormid risks to be acceptable and the effect of submission of the required data on the assessment of dichlormid risk will be to lower estimated risks (due to the removal of additional safety factors), EPA is relying on that prior risk assessment and the findings in the prior dichlormid FR notices, subject to one modification, to demonstrate the safety of the tolerances established in this action. The one modification of the prior risk assessment and FR notices is to update how exposure to dichlormid in drinking water is factored into the risk assessment.

Previously, EPA assessed aggregate exposure (food and drinking water) to dichlormid using the DWLOC (drinking water level of comparison) approach. The DWLOC is the concentration of a chemical in drinking water that would be acceptable as an upper limit considering total aggregate exposure to that chemical from food, water, and residential sources. In this case, there are no residential uses of dichlormid. Acute and chronic aggregate risks from dichlormid exposure were assessed by comparing the calculated DWLOCs to the estimated environmental concentrations (EECs) of dichlormid in

surface water and groundwater. Since the EECs (< 1 ppm in both surface and groundwater) were well below the calculated DWLOCs for acute exposure (73 parts per billion (ppb)) and chronic exposure (20 ppb), acute and chronic aggregate risks were determined to be below the Agency’s level of concern. Details of the risk assessment for dichlormid may be found in the document “Human Health Risk Assessment for Dichlormid-Request for Establishing Permanent Tolerances for Dichlormid on Corn,” which is available in docket ID number EPA-HQ-OPP-2005-0477.

The Agency no longer uses the DWLOC approach for assessing aggregate exposure to pesticides. Rather, estimated drinking water concentrations (EDWCs) are directly entered into the dietary exposure model to assess the contribution of drinking water exposure to aggregate exposure. EPA then determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. Using this approach, together with the conservative assumptions and SFs discussed earlier in this unit, EPA has concluded that acute and chronic exposure to dichlormid from food and water will utilize 56% of the aPAD and 34% of the cPAD for infants, less than one year old, the population group receiving the greatest exposure.

Based on the prior and updated risk assessments as well as the findings in the prior dichlormid FR notices, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to dichlormid residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with nitrogen selective thermionic detection) is available to enforce the tolerance 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](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits

(MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for dichlormid in or on corn commodities.

#### C. Response to Comments

An anonymous comment was received objecting to the presence of any pesticide residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the FFDCA contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

#### D. Revisions to Petitioned-for Tolerances

EPA is revising the requested tolerance expression to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the tolerances cover residues of the herbicide safener dichlormid, including its metabolites and degradates, but that compliance with the tolerances is to be determined by measuring only dichlormid (2,2-dichloro-*N,N*-di-2-propenylacetamide). EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

#### V. Conclusion

Therefore, tolerances are established for residues of dichlormid, including its metabolites and degradates, in or on

corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover at 0.05 ppm. Compliance with the tolerances is to be determined by measuring only dichlormid (2,2-dichloro-*N,N*-di-2-propenylacetamide).

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 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 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) (Pub. L. 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).

#### VII. 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: March 8, 2011.

**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 180.469 is amended by revising paragraph (a) to read as follows:

#### **§ 180.469 Dichlormid; tolerances for residues.**

(a) *General.* Tolerances are established for residues of dichlormid, including its metabolites and degradates, when used as an inert ingredient (herbicide safener) in pesticide formulations, in or on the commodities in the following table.

Compliance with the tolerances is to be determined by measuring only dichlormid (2,2-dichloro-*N,N*-di-2-propenylacetamide).

Commodity	Parts per million
Corn, field, forage .....	0.05
Corn, field, grain .....	0.05
Corn, field, stover .....	0.05
Corn, pop, grain .....	0.05
Corn, pop, stover .....	0.05
Corn, sweet, forage .....	0.05
Corn, sweet, kernel plus cob with husks removed .....	0.05
Corn, sweet, stover .....	0.05

\* \* \* \* \*

[FR Doc. 2011-6440 Filed 3-22-11; 8:45 am]

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**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 217**

[Docket No. 100806326-1088-02]

RIN 0648-AY99

**Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Space Vehicle and Missile Launch Operations at Kodiak Launch Complex, AK**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS, upon application from the Alaska Aerospace Corporation (AAC), is issuing regulations to govern the unintentional taking of small numbers of marine mammals incidental to rocket launches from the Kodiak Launch Complex (KLC) on Kodiak Island, AK. Issuance of regulations is required by the Marine Mammal Protection Act (MMPA) when the Secretary of Commerce (Secretary), after notice and opportunity for comment, finds, as here, that such takes will have a negligible impact on the species and stocks of marine mammals and will not have an unmitigable adverse impact on their availability for subsistence uses. These regulations do not authorize the AAC's rocket launch activities; such authorization is not within the jurisdiction of the Secretary. Rather, these regulations govern the issuance of Letters of Authorization (LOAs) for the unintentional and incidental take of marine mammals in connection with

this activity and prescribe methods of taking and other means of effecting the least practicable adverse impact on marine mammal species and their habitat, and on the availability of the species for subsistence uses. In addition, NMFS incorporates reporting and monitoring requirements on these activities.

**DATES:** Effective March 22, 2011 to March 22, 2016.

**ADDRESSES:** A copy of the AAC's application and other related documents may be obtained by writing to P. Michael Payne, Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910-3225, by telephoning the contact listed under **FOR FURTHER INFORMATION CONTACT**, or on the Internet at: <http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications>. Documents cited in this final rule may also be viewed, by appointment, during regular business hours at the above address.

**FOR FURTHER INFORMATION CONTACT:** Michelle Magliocca, Office of Protected Resources, NMFS, 301-713-2289, ext 123.

**SUPPLEMENTARY INFORMATION:**

**Background**

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the identified species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth in the regulations. NMFS has defined "negligible impact" in 50 CFR 216.103 as " \* \* \* an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the

species or stock through effects on annual rates of recruitment or survival."

Except with respect to certain activities not pertinent here, the MMPA (16 U.S.C. 1362(18)(A)) defines "harassment" as:

Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

**Summary of Request**

On June 4, 2010, NMFS received a complete application for regulations from AAC for the taking of small numbers of marine mammals incidental to launching space launch vehicles, long-range ballistic target missiles, and other smaller missile systems at the KLC. A proposed rule was published on December 23, 2010 (75 FR 80773). NMFS received 12 comments on the proposed rule from eight private citizens, the Kodiak Chamber of Commerce, the Kodiak Island Borough Mayor, the City of Kodiak Mayor, and the Marine Mammal Commission (Commission). The majority of the comments supported the proposed rule. These regulations will allow NMFS to issue Letters of Authorization (LOAs) to the AAC over a 5-year period. A full description of the operations is contained in the AAC's application which is available upon request (*see ADDRESSES*) or at: <http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications>.

The AAC conducts space vehicle and missile launches from the KLC, a commercial spaceport that supports civilian and Federal launch customers. The facility occupies 3,717 acres of State-owned lands on the Narrow Cape Peninsula on the eastern side of Kodiak Island, Alaska. The KLC primarily supports launches of small to medium space launch vehicles—which are those used to boost satellites to orbit—ranging in size from the small space-launch Castor 120 motor (used in the Athena, Minotaur IV, Minotaur V, and Taurus I systems) to the under-development medium-lift Taurus II. The KLC is also configured to support launch of the Minuteman I-derived Minotaur I Space Launch System, and to support the launch of long-range ballistic systems such as the Polaris derived A-3 STARS, the Minuteman-derived Minotaur II and III, and the C-4. Launch operations are authorized under license from the Federal Aviation Administration (FAA),