Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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.

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 5, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: September 23, 2016.

Alexis Strauss,

Acting Regional Administrator, EPA Region 9.

[FR Doc. 2016–24082 Filed 10–5–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0121; FRL–9951–90]

Dichlormid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dichlormid in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor. Drexel Chemical Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 6, 2016. Objections and requests for hearings must be received on or before December 5, 2016, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0121, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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–2016–0121 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 December 5, 2016. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0121, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of April 25, 2016 (81 FR 24044) (FRL–9944–86), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP IN–10858) by Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–03227. Although the notice announced the petition requested that 40 CFR 180.469 be amended by establishing tolerances for residues of the inert ingredient (safener) dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 parts per million (ppm), the notice of filing submitted simply listed numerous commodities that were intended to correspond to the commodities for which metolachlor and s-metolachlor tolerances were established. That document referenced a summary of the petition prepared by Drexel Chemical Company, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

To ensure consistency between the notice of filing and the petition filed and to avoid any confusion, EPA requested that Drexel revise and resubmit their notice of filing to clarify that the request is to establish tolerances for residues of the inert ingredient (safener) dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 ppm. Upon receiving that revised petition, EPA issued a notice of filing of that petition pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3) in the **Federal Register** of July 20, 2016 (81 FR 47150) (FRL–9948–45). The petition requested that 40 CFR 180.469 be amended by establishing tolerances for residues of the inert ingredient (safener) dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 ppm. That revised petition prepared by Drexel Chemical Company, the registrant, is available in the docket, *http://www.regulations.gov.* There was one comment received in response to this notice of filing; however, the comment was not related to this chemical or petition and is therefore, not relevant to this action.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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 database for dichlormid has been previously reviewed by the Agency, most recently March 23, 2011 when the permanent tolerance for dichlormid was issued (76 FR 16308) (FRL–8866–2). No new data was reviewed as part of this petition for tolerance.

Specific information on the studies received and the nature of the adverse effects caused by dichlormid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In acute toxicity studies, dichlormid exhibits low to moderate toxicity, depending on the route of exposure. The oral lethal dose $(LD)_{50}$ for dichlormid in rats is 2,816 milligram/kilogram (mg/kg) in males and 2,146 mg/kg for females (Category III). The dermal LD_{50} of dichlormid in rats is greater than 2,000 mg/kg (Category III). The acute inhalation lethal concentration $(LC)_{50}$ in rats is greater than 5.5 mg/(L) (Category IV). Dichlormid is mildly irritating to the skin of rabbits (Category IV) and severely irritating to the eyes of rabbits

(Category II). Dichlormid is a mild dermal sensitizer.

The liver is the target organ in subchronic and chronic toxicity studies in rats and dogs. There are two 90-day rat toxicity studies are available. One older study (1972), was determined to be an unacceptable study. In the other study, toxicity was manifested as minor decreased in body weight gains and food efficiency in females and on increased liver weight and a slightly increased (not statistically significant) incidence of liver lipidosis in males. Similarly two 90-day toxicity studies in dogs are available. In the newer study, via capsules, decreased body weight gains, hematological and clinical chemistry alternations, liver toxicity and voluntary muscle pathological changes were observed. In a 1-year toxicity study in the dogs, voluntary muscle fiber degeneration and slight to moderate vacuolation of the adrenal cortex was observed at 20 mg/kg/day. There was also increased in alkaline phosphatase activity in both sexes and decreased in aspartate aminotransferase activity in females. Liver weights (absolute and relative to body) were increased in both sexes.

In a developmental toxicity study in rats, decreased mean absolute body weights, body weight gains, and food consumption was observed in maternal animals. Developmental toxicity in rats was manifested as marginal increased in skeletal anomalies in the presence of maternal toxicity. In the developmental toxicity study in rabbits, increased incidence of alopecia and decreased mean maternal body weight gains and food consumption was observed in maternal animals. The fetal effects in rabbits, exhibited in the presence of maternal toxicity, were manifested as increases in post-implantation loss accompanied by an increase number of resorptions/doe (both early and late resorptions), decreased number of live/fetuses/litter, and slightly decreased mean fetal body weights. In a 2-generation reproduction study in rats, no treatment related effects on reproductive parameters were observed. Minimal increased liver weight, minimal decreased weight gain and minimal decreased in food consumption was observed in parental animals. Increased liver weights were observed in the offspring.

No increased incidences of treatment related tumors were observed in mice and rats. In the carcinogenicity study in mice, kidney changes and changes in reproductive organs were observed, while rats exhibited decreased body weights and liver toxicity. Mutagenic potential for dichlormid was evaluated in an adequate battery of *in vivo* and *in vitro* assays. A negative response was observed in these assays except in one *in vitro* assay (mouse lymphoma assay). However, the *in vivo* mouse micronucleus assay was negative.

In an acute neurotoxicity study in rats, decreased body weight gains with lower food consumption was observed in both sexes. Functional observational battery (FOB) measurements at the time of peak effect (4 hrs post dose) showed decreased activity, hunching, increased touch response, lachrimation, piloerection, reduced splay reflex, and signs of salivation. These effects were deemed slight with a greater incidence in females. No treatment-related changes in bodyweight, food consumption, FOB, motor activity, brain weight, or neuropathology were identified in the 90-day neurotoxicity study in rats; however, the high dose of 750 ppm (equal to 55.4 mg/kg/day) was not considered as adequate for testing. No evidence of immunotoxicity was observed in a dietary immunotoxicity study in rats. There were no treatment related effects on spleen and thymus weights at any of the doses of dichlormid tested.

Approximately 90% of the orally administered dose was absorbed in rats. Urinary excretion was the major route of elimination of orally administered dichlormid, consistently accounting for 60–78% of the administered dose over 48–168 hours following a single oral dose. Fecal excretion accounted for ~8–20% of a single oral dose. Approximately 70–77% of urinary excretion (representing 52–54% of the administered dose) occurred within 24 hours. No gender-related difference in rate or amount of urinary excretion was observed. No significant accumulation in the body was observed. Dichlormid was metabolized via two pathways:

1. Initial dechlorination followed by formation of various chlorinated, water-soluble metabolites, and;

2. Formation of various chlorinated metabolites.

In a subchronic inhalation toxicity study in rats via whole body exposure for 6 hours a day, 5 days/week for 14 weeks, decreased body weights and increased liver weights were observed at the highest dose tested. The increased liver weights was considered as an adaptive response. Chromorhinorrhea, a respiratory system clinical observation based on the discharge of colored secretion from the nostrils, was exhibited consistently in the two top dose exposure groups. Microscopic pathology identified in the two top dose exposure groups, dose-dependent respiratory tract tissue alterations involving the olfactory epithelium for both genders.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for dichlormid used for human health risk assessment are shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DICHLORMID USE IN HUMAN RISK ASSESSMENT [1]

Exposure scenario	Dose and factors	FQPA SF and endpoint for risk assessment	Study and toxicological effects
Acute Dietary, *all populations* including infants and children.	NOAEL = 10 mg/kg UF = 100 Acute RfD = 0.10 mg/kg/day	FQPA SF = 1 ..... aPAD = acute RfD/ FQPA SF = 0.10 mg/kg/day	Developmental Toxicity Study—Rat Maternal LOAEL = 40 mg/kg/day based on decreased body weight gain and food consumption (most significant on days 7–10 of dosing).
Chronic Dietary, *all populations*	NOAEL = 5 mg/kg/ day. UF = 100 Chronic RfD = 0.05 mg/kg/day.	FQPA SF = 1 ..... cPAD = chr RfD/ FQPA SF = 0.05 mg/kg/day.	1-year Study—Dog LOAEL = 20 mg/kg/day (male, female), based on increased liver weights, increased in alkaline phosphatase activity, minimal muscle fiber degeneration in, slight to moderate vacuolation of the inner cortex of the adrenal gland, and increased kidney weights (females).
Dermal Absorption	100% default; neither a dermal absorption study nor a dermal toxicity study (for extrapolation) is available in the database.		
Short-term Dermal	Oral NOAEL = 10.0 mg/kg/day.	MOE = 100	Developmental toxicity Study—Rats Maternal LOAEL = 40 mg/kg/day based on decreased body weight gain and food consumption (most significant on days 7–10 of dosing). This dose/endpoint/study was used for deriving the aRfD. Dermal toxicity study is not available. 100% dermal absorption factor should be used for this risk assessment.
Intermediate- and Long-Term (Dermal).	Oral NOAEL = 5 mg/ kg/day.	MOE = 100	1-year study—Dog LOAEL = 20 mg/kg/day (male, female), based on increased liver weights, increased in alkaline phosphatase activity, minimal muscle fiber degeneration in, slight to moderate vacuolation of the inner cortex of the adrenal gland, and increased kidney weights (females).
Inhalation (All Durations)	2 μg/L	MOE = 100	14-week inhalation study LOAEL = 20 μg/L based on clinical signs, increased liver and kidney weights, gross pathology and non-neoplastic histopathology. The route of exposure in this study is appropriate for this risk assessment.
Cancer	.....	.....	No evidence of carcinogenicity in rats and mice.

[1] UF = uncertainty factor; FQPA SF = FQPA Safety Factor; NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; PAD = population adjusted dose (a = acute, c = chronic); RfD = reference dose; LOC = level of concern; MOE = margin of exposure.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dichlormid, EPA considered exposure under the petitioned-for tolerances as well as all existing dichlormid tolerances in 40 CFR 180.469. The assessment was conducted using the proposed tolerance of 0.05 ppm for those commodities for which there is a current tolerance for metolachlor and S-metolachlor as well as for all commodities to account for the potential dietary exposure that could result from dichlormid should additional tolerances be established for metolachlor and S-metolachlor. EPA assessed dietary exposures from dichlormid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for dichlormid. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues (*i.e.,* 0.05 ppm) and 100% crop treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 CSFII. As to residue levels in food, EPA used tolerance level residues (*i.e.,* 0.05 ppm) and 100% crop treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that dichlormid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for dichlormid. Tolerance level residues (*i.e.,* 0.05 ppm) and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* For the current screening level dietary risk assessment, to support the request for expanded tolerances for dichlormid, a conservative drinking water concentration value of 100 parts per billions (ppb), based on screening level modeling, was used to account for the contribution of the additional commodities to drinking water for the chronic dietary risk assessments for the parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Dichlormid is not contained in any pesticide formulation registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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.''

EPA has not found dichlormid to share a common mechanism of toxicity with any other substances, and dichlormid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dichlormid does not have 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of infants and children from *in utero* exposure to dichlormid based on developmental toxicity study in rats. In this study the developmental toxicity was manifested as marginal increased in skeletal anomalies (developmental toxicity NOAEL 40 mg/kg/day) at a one dose higher than the NOAEL for maternal toxicity (NOAEL 10 mg/kg/day). There is qualitative evidence of increased susceptibility demonstrated following *in utero* exposure in the prenatal developmental toxicity study in rabbits, since fetal effects observed (resorptions, decreased live fetuses per litter, and decreased fetal body weight) are considered to be more severe than those observed in maternal animals (increased alopecia, decreased body weight gain and food consumption). In this study the NOAEL for maternal and developmental toxicity is 30 mg/kg/day. There is no evidence increased susceptibility of infants and children from pre-and post-natal exposure to dichlormid in the two generation reproduction study. In this study, increased liver, weights, decreased body weight gain and decreased food consumption was observed in parental animals and increased liver weights in the offspring.

There is no/low concern for increased qualitative susceptibility seen in the developmental toxicity study in rabbits because there is well characterized NOAEL for the developmental toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for dichlormid is complete. All part 158 data requirements are fulfilled. The dichlormid toxicity database included subchronic studies in rats and dogs, mutagenicity battery, carcinogenicity studies in mice and rats, developmental toxicity study in rats and rabbits, 2-generation reproduction study, acute and subchronic neurotoxicity study, immunotoxicity study, metabolism and repeat dose inhalation toxicity study.

ii. There is no indication that dichlormid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity based on acute and subchronic neurotoxicity study.

iii. There is no evidence that dichlormid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. There was some evidence of increased qualitative susceptibility seen in the developmental toxicity study in rabbits, however, there is no residual uncertainty or concern because there is well characterized NOAEL for the developmental toxicity and regulatory end points are below the NOAEL for the developmental effects thus providing additional margin of safety.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dichlromid in drinking water. These assessments will not underestimate the exposure and risks posed by dichlromid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dichlormid will occupy 26.2% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dichlormid from food and water will utilize 15.3% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for dichlormid.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, dichlormid is not contained in any pesticide product registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for dichlormid.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, dichlormid is not contained in any pesticide product registered for any use patterns that would result in intermediate-term

residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for dichlormid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity, dichlormid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, 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; email address: *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 United Nations 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.

V. Conclusion

Therefore, tolerances are established for residues of dichlormid, in or on all commodities for which there is a tolerance for metolachlor and S-metolachlor at 0.05 ppm as listed in 40 CFR 180.368.

VI. Statutory and Executive Order Reviews

This action establishes tolerances 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 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.

This action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: September 27, 2016.

Michael Goodis,

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), 346a and 371.

■ 2. In § 180.469, redesignate the existing paragraph (a) as (a)(1), and add paragraph (a)(2) to read as follows:

§ 180.469 Dichlormid; Tolerances for residues.

(a) *General.* (1) * * *

(2) Tolerances are established for residues of dichlormid, including its metabolites and degradates, at 0.05 parts per million (ppm) when used as an inert ingredient (herbicide safener) in pesticide formulations containing metolachlor or S-metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor or S-metolachlor. Compliance with the tolerances is to be determined by measuring only

dichlormid (2,2-dichloro-*N,N*-di-2-propenylacetamide).

* * * * *

[FR Doc. 2016–24214 Filed 10–5–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[EPA–R09–RCRA–2015–0445; FRL–9953–45–Region 9]

Final Determination To Approve Site-Specific Flexibility for Closure and Monitoring of the Picacho Landfill

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency, Region IX, is making a final determination to approve two Site-Specific Flexibility Requests (SSFRs) from Imperial County (County or Imperial County) to close and monitor the Picacho Solid Waste Landfill (Picacho Landfill or Landfill). The Picacho Landfill is a commercial municipal solid waste landfill (MSWLF) operated by Imperial County from 1977 to the present on the Quechan Indian Tribe of the Fort Yuma Indian Reservation in California.

EPA is promulgating a site-specific rule proposed on April 7, 2016, that approves an alternative final cover and a modification to the prescribed list of groundwater detection-monitoring parameters for ongoing monitoring for the Picacho Landfill.

DATES: This final rule is effective on October 6, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R09–RCRA–2015–0445. All documents in the docket are listed in the *http://www.regulations.gov* index. Publicly available docket materials are available electronically in *http://www.regulations.gov* and in hard copy at the EPA Library, located at the Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, California. The EPA Library is open from 9:00 a.m. to 4:00 p.m., Monday through Thursday, excluding legal holidays, and is located in a secured building. To review docket materials at the EPA Library, it is recommended that the public make an appointment by calling (415) 947–4406 during normal business hours. Copying arrangements will be made through the EPA Library and billed directly to the recipient. Copying costs may be waived depending on the total number of pages copied.

FOR FURTHER INFORMATION CONTACT: Steve Wall, Land Division, Mail Code LND 2–3 U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105–3901; telephone number: (415) 972–3381; fax number: (415) 947–3564; email address: *wall.steve@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What did EPA propose?

After completing a review of Imperial County's Picacho Landfill Final Closure/Post-Closure Maintenance Plan and the associated SSFRs, EPA proposed this rulemaking in the **Federal Register**. The proposed determination was published at 81 FR 20274, April 7, 2016. EPA proposed to approve an alternative final cover that varies from the final closure requirements of 40 CFR 258.60(a) but meets the criteria at 40 CFR 258.60(b), and alternative groundwater detection monitoring parameters for post-closure monitoring in accordance with 40 CFR 258.54(a).

II. Legal Authority for This Action

Under sections 1008, 2002, 4004, and 4010 of the Resource Conservation and Recovery Act of 1976 (RCRA) as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6901 *et seq.,* Congress required EPA to establish revised minimum federal criteria for MSWLFs, including landfill location restrictions, operating standards, design standards, and requirements for ground water monitoring, corrective action, closure and post-closure care, and financial assurance. Under RCRA section 4005, states are to develop permit programs for facilities that may receive household hazardous waste or waste from conditionally exempt small quantity generators of hazardous waste, and EPA is to determine whether the state's program is adequate to ensure that such facilities will comply with the revised federal criteria.

The MSWLF criteria are set forth in the Code of Federal Regulations at 40 CFR part 258. These regulations are prescriptive, self-implementing and apply directly to owners and operators of MSWLFs. Many of these criteria include a flexible performance standard as an alternative to the prescriptive, self-implementing regulation. The flexible standard is not self-implementing, and requires approval by the Director of an EPA-approved state MSWLF permitting program. However, EPA's approval of a state program generally does not extend to Indian Country because states generally do not have authority over Indian Country. For this reason, owners and operators of MSWLF units located in Indian Country cannot take advantage of the flexibilities available to those facilities that are within the jurisdiction of an EPA-approved state program. However, the EPA has the authority under sections 2002, 4004, and 4010 of RCRA to promulgate site-specific rules to enable such owners and operators to use the flexible standards. See *Yankton Sioux Tribe* v. *EPA,* 950 F. Supp. 1471 (D.S.D. 1996); *Backcountry Against Dumps* v. *EPA,* 100 F.3d 147 (D.C. Cir. 1996). EPA refers to such rules as ''Site-Specific Flexibility Determinations.'' EPA has developed guidance for owners and operators on preparing a request for such a site-specific rule, entitled ''Site-Specific Flexibility Requests for Municipal Solid Waste Landfills in Indian Country, Draft Guidance,'' EPA530–R–97–016 (August 1997) (Draft Guidance).

III. Background

The Picacho Landfill is located on Quechan tribal lands on the Fort Yuma Indian Reservation approximately four miles north-northeast of the community of Winterhaven, in Imperial County, California. The Picacho Landfill is a commercial MSWLF operated by Imperial County from 1977 to the present. The landfill site is approximately 12.5 acres.

In January 2006, the Tribe requested that EPA provide comments on the County's closure plan. Between 2006 and 2011, EPA worked with the Tribe, the Bureau of Indian Affairs (BIA) and the County to develop the closure plan. During this time, EPA also reviewed the SSFRs to determine whether they met technical and regulatory requirements. On October 27, 2010, Imperial County submitted its Picacho Final Closure/Post-Closure Maintenance Plan. EPA provided a final round of comments on February 10, 2011, which Imperial County incorporated as an addendum. On April 30, 2012, the Tribe approved the Picacho Landfill Final Closure/Post-Closure Maintenance Plan as amended, and, pursuant to EPA's Draft Guidance, the Tribe forwarded to EPA two SSFRs that had been submitted by Imperial County to close and monitor the Picacho Landfill. The requests sought EPA approval to use an alternative final cover meeting the performance requirements of 40 CFR 258.60(a), and to modify the prescribed list of groundwater detection-monitoring parameters provided in 40 CFR 258.54(a)(1) and (2) for ongoing monitoring.