

1999 and amended on September 3, 2004.

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[FR Doc. E9-10520 Filed 5-5-09; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0105; FRL-8409-1]

#### Morpholine 4-C<sub>6-12</sub> Acyl Derivatives; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of Morpholine 4-C<sub>6-12</sub> Acyl derivatives (CAS Reg. No. 887947-29-7), herein referred to in this document as morpholine amide when used as the inert ingredient in pesticide formulations applied in or on growing crops. Huntsman Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of morpholine amide.

**DATES:** This regulation is effective May 6, 2009. Objections and requests for hearings must be received on or before July 6, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0105. 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:** Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8353; e-mail address: [debesai.alganesh@epa.gov](mailto:debesai.alganesh@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the

submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0105 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 July 6, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2008-0105, by one of the following methods:

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

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

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

##### II. Background and Statutory Findings

In the **Federal Register** of June 13, 2008 (73 FR 33814) (FRL-8367-3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Pub. L. 104-170), announcing the filing of a pesticide petition (PP 6E7093) by Huntsman Corporation, 8600 Gosling Road, The Woodlands, TX 77381. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of Morpholine 4-C<sub>6-12</sub> Acyl derivatives (CAS Reg. No. 887947-29-7), herein referred to in this document as morpholine amide when used as inert ingredient in pesticide formulations applied in or on growing crops. That notice included a summary of the petition prepared by the petitioner.

There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the 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. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own):

Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

### IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity,

completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by morpholine amide is discussed in this unit.

The following provides a brief summary of the risk assessment and conclusions for the Agency's review of morpholine amide. The Agency's full decision document for this action is available in the Agency's electronic docket (regulations.gov) under the docket number EPA-HQ-OPP-2008-0105. The toxicological database for morpholine amide (CAS Reg. No. 887947-29-7) is limited; however, adequate studies are available on the structurally related compound, lauric DEA. Like lauric DEA, morpholine amide is expected to be readily absorbed and metabolized to succinic and adipic morpholine amide. Free fatty acids, mainly capric and caprylic acid as well as morpholine are expected to be potential impurities (minute quantity). Adequate toxicological information is available on these metabolites and impurities. The toxicological database on morpholine amide consists of: An acute toxicity battery, a mutagenicity battery and a reproductive and developmental screening study in rats (including neurotoxicity screening). There are no long term or carcinogenicity studies available on morpholine amide. However, studies on the structurally similar compound lauric DEA included two oral subchronic studies in rats, one subchronic study in dogs, a mutagenicity battery, a metabolism study, and subchronic and carcinogenicity studies in rats and mice via the dermal route of exposure. In addition, many subchronic and chronic studies are available on morpholine (a manufacturing impurity). EPA has toxicological data on fatty acids and caprylic acid, a potential metabolite of morpholine amide. Taking all these studies into consideration, EPA concluded that these studies can be used to evaluate the toxicity of morpholine amide. Other than the chronic studies, all other data are adequate to characterize the potential toxicity of morpholine amide.

Animal studies show that morpholine amide has low acute toxicity (oral LD<sub>50</sub> in the rat > 2,000 milligram/kilograms (mg/kg) and inhalation LC<sub>50</sub> in the rat > 2.0 mg/L). Although morpholine amide was a mild eye irritant in the rabbit, it was not a skin irritant (rabbit). It was

positive for skin sensitization in the Guinea pig. Based upon the metabolism and low toxicity characteristics of lauric DEA, subchronic and chronic toxicity of morpholine amide is also expected to be low. Although no specific neurotoxicity studies were performed, in the combined repeated dosed reproductive and developmental toxicity screening test, potential indications of neurotoxicity such as lethargy and altered functional observation battery (FOB) parameters were observed at a high dose of 600 mg/kg/day. However, these clinical signs were judged to be to high dose toxicity rather than as a result of a neurotoxic reaction. Moreover, since the toxic effects were seen only at a high dose, the NOAEL (200 mg/kg/day) will be protective from these effects (three fold lower than the dose that produced clinical signs of neurotoxicity). Additionally, the slight decrease in relative brain weight ( $\leq 6\%$ ) in the reproductive and developmental screening study was not considered as the toxicologically relevant effect because the absolute brain weight was not affected, there were no pathological findings and this slight change in relative brain weight is considered due to changes in body weight at 600 mg/kg/day.

No fetal effects were seen in a combined repeat dose reproductive and developmental toxicity study in Wistar Hannover rats at doses that produced maternal toxicity (lethargy and alterations in functional observational parameters). No treatment-related effects were observed for any reproductive or litter parameters at any dose level. The NOAEL for systemic toxicity is 200 mg/kg/day. The NOAEL for both reproductive and developmental toxicity is 600 mg/kg/day (the highest dose tested (HDT)). Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to morpholine amide when used as an inert ingredient in pesticide formulations applied to growing crops.

Based on negative response of morpholine amide in mutagenicity, equivocal evidence of carcinogenic activity of lauric DEA (dermal route, only one species, one sex), lack of carcinogenicity of impurity (morpholine) and other metabolites, EPA concluded that morpholine amide is not likely to be carcinogenic.

The free fatty acid impurities on the subject chemical are not likely to impart any significant toxicity. Fatty acid salts have been reported to have a low acute toxicity. A chronic inhalation exposure of rats to morpholine, a potential impurity of the subject chemical for 2 years at concentration of 150 parts per

million (approximately 533 mg/m<sup>3</sup>) or less revealed no carcinogenic potential or chronic systemic toxicity. Consistent with its known irritating properties, morpholine produced only local irritation, which was limited almost exclusively to high dose animals.

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs.

Morpholine amide's acute toxicity is so low that it is not expected to pose an acute risk and derivation of an aPAD is unnecessary. A cPAD of 0.67 mg/kg/day was derived from the NOAEL of 200 mg/kg/day for the systemic toxicity seen in the reproductive and developmental toxicity study. A safety factor of 300 (10x for interspecies and 10x for intra-species variations and additional 3X FQPA safety factor for the lack of chronic study) was used.

#### V. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably

foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

In the absence of actual residue data for morpholine amide, the Agency performed a dietary (food and drinking water) exposure assessment for morpholine amide for the proposed pre-harvest use using worst case assumptions. These assumptions included that:

1. Morpholine amide would be used as an inert ingredient in all food use pesticide formulations applied to all crops,

2. One hundred percent of all food crops would be treated with pesticides containing morpholine amide,

3. Morpholine amide residues would be present in all crops at levels equal to or exceeding the highest established tolerance levels for any pesticide active ingredient for pre-harvest uses, and

4. A conservative default value of 1,000 parts per billion for the concentration of an inert ingredient in all sources of drinking water was used. This approach is highly conservative as it is extremely unlikely that morpholine amide would have such use as a pesticide product inert ingredient and be present in food commodities and drinking water at such high levels.

#### VI. Cumulative Effects

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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to morpholine amide and any other substances, and these chemicals do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action,

therefore, EPA has not assumed that these chemicals 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of toxicity at <http://www.epa.gov/pesticides/cumulative/>.

#### VII. Additional Safety Factor for the Protection of Infants and Children

Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. EPA concluded that the FQPA safety factor for morpholine amide should be reduced to 3X for the following reasons.

1. Although the toxicological database on morpholine amide is limited, studies on the structurally similar compound lauric DEA are available. These studies include two oral subchronic studies in rats, one subchronic study in dogs, mutagenicity battery, metabolism study, and subchronic and carcinogenicity studies in rats and mice via dermal route of exposure. In addition, many subchronic and chronic studies are available on morpholine (a manufacturing impurity). EPA does not have a chronic toxicity study for either morpholine amide or lauric DEA. This lack of a chronic study is largely offset by the results of the Organization for Economic Cooperation and Development (OECD) reproduction/developmental screening toxicity study – which showed no target organ toxicity at doses up to 600 mg/kg/day – and the existing subchronic data.

2. EPA concluded that there is no evidence of increased susceptibility to infants and children. No fetal effects were seen in the combined repeated dosed reproductive and developmental toxicity study in Wistar Hannover rats at doses that produce maternal toxicity (lethargy and alterations in functional observational parameters). No treatment-related effects were observed for any reproductive or litter parameters at any dose level. The NOAEL for systemic toxicity is 200 mg/kg/day. The NOAEL for both reproductive and

developmental toxicity is 600 mg/kg/day (the HDT). No developmental toxicity study in rabbit is available in the morpholine amide database. However, EPA concluded that the developmental toxicity study in rabbits is not likely to provide lower endpoint than the endpoint selected for the risk assessment since no developmental or reproductive toxicity was observed in rats at doses up to and including 600 mg/kg/day.

3. There is low concern that morpholine amide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. As noted, the slight decrease in relative brain weight ( $\leq 6\%$ ) in the OECD reproductive/developmental screening toxicity study in rats was not considered as the toxicologically relevant effect and the clinical signs (lethargy and altered FOB parameters) in the OECD reproductive/developmental screening study in rats are considered to be due to high dose toxicity.

4. In the absence of actual exposure data on morpholine amide, a highly conservative exposure estimate using default parameters is not likely to underestimate risk to infants and children.

Although there is some uncertainty due to the absence of a chronic study and a rabbit developmental study, there is low concern that risks will be underestimated due the results of the OECD reproduction/developmental screening toxicity study showing no organ toxicity at high doses, the lack of a finding of developmental toxicity in that study, and the very conservative exposure assessment that has been conducted for morpholine. Nonetheless, a FQPA safety factor of 3X is being retained, primarily due to the absence of a chronic toxicity study.

### VIII. Determination of Safety for U.S. Population

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate uncertainty/safety factors. EPA calculates the aPAD and cPAD by dividing the POD by all applicable uncertainty/safety factors.

As noted in this unit, morpholine amide is not expected to pose an acute risk. To evaluate chronic risk, EPA compared estimated chronic exposure to the cPAD of 0.67 mg/kg/day. Utilizing a highly conservative aggregate exposure assessment, the resulting chronic

exposure estimates do not exceed the Agency's level of concern ( $<100\%$  cPAD). Children 1–2 years old were the most highly exposed population with the chronic exposure estimate occupying 67.6% of the cPAD. In addition, this highly conservative exposure assessment is protective of any possible non-occupational exposures to morpholine amide as it results in exposure estimates orders of magnitude greater than the high-end exposure estimates for residential uses of pesticides routinely used by EPA.

Taking into consideration all available information on morpholine amide, it has been determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to this chemical. Therefore, the exemption from the requirement of a tolerance for residues of morpholine amide (CAS Reg. No. 887947–29–7), when used as inert ingredient in pre-harvest applications, under 40 CFR 180.920 can be considered safe under section 408(q) of the FFDCA.

### IX. Other Considerations

#### A. Analytical Method

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### B. Existing Exemptions

There are no existing exemptions for morpholine amide.

#### C. International Tolerances

The Agency is not aware of any country requiring a tolerance for morpholine amide nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

### X. Conclusions

Therefore, a tolerance exemption is established for morpholine amide (CAS Reg. No. 887947–29–7) when used as inert ingredient in pesticide formulations applied to growing crops only.

### XI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under

Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the 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) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

**XII. 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: April 17, 2009.

**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. In § 180.920, the table is amended by adding alphabetically the following inert ingredient to read as follows:

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

Inert ingredients	Limits	Uses
* * *	*	*
Morpholine 4-C <sub>6-12</sub> Acyl Derivatives (CAS Reg. No. 887947-29-7)	*	As a solvent
* * *	*	*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0166; FRL-8409-8]

**Novaluron; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of novaluron in or on strawberry. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on strawberries. This regulation establishes a maximum permissible level for residues of novaluron in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2011.

**DATES:** This regulation is effective May 6, 2009. Objections and requests for hearings must be received on or before July 6, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0166. All documents in the docket are listed in the docket index available in <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:** Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; e-mail address: [ertman.andrew@epa.gov](mailto:ertman.andrew@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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*C. Can I File an Objection or Hearing Request?*

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