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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180****[OPP-301162; FRL-6797-2]****RIN 2070-AB78****Propamocarb Hydrochloride; Pesticide Tolerances for Emergency Exemptions****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation revises time-limited tolerances for residues of propamocarb hydrochloride in or on tomato and tomato, paste and revokes the time limited tolerance for residues of propamocarb hydrochloride in or on tomato, puree. 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 tomatoes. This regulation revises maximum permissible levels for residues of propamocarb hydrochloride in these food commodities. The revised tolerances will expire and are revoked on December 31, 2003.

DATES: This regulation is effective September 21, 2001. Objections and requests for hearings, identified by docket control number OPP-301162, must be received by EPA on or before November 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301162 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 308-9364; and e-mail address: pemberton.libby@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 categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301162. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information

claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is revising the tolerances for residues of the fungicide propamocarb hydrochloride, propyl [3-(dimethylamino)propyl] carbamate monohydrochloride, by increasing the residue levels in or on tomato and tomato, paste, to 2 and 5 ppm, respectively, and removing the level for tomato, puree. These revised tolerances will expire and are revoked on December 31, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section

408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Propamocarb hydrochloride on Tomato and FFDCA Tolerances

Failure to control late blight in tomatoes with the registered fungicides have been caused almost exclusively by immigrant strains of late blight (*Phytophthora infestans*), which are resistant to the control of choice, metalaxyl. Before the immigrant strains of late blight arrived, all of the strains in the United States were previously controlled by treatment with metalaxyl. Presently, there are no fungicides registered in the United States that will provide adequate control of the immigrant strains of late blight. EPA has authorized under FIFRA section 18 the use of propamocarb hydrochloride on tomato for control of late blight in California. After having reviewed the submission, EPA concurs that an emergency condition exists for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of propamocarb hydrochloride in or on tomato and tomato paste. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is revising these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on tomato and tomato paste after that

date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed the levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether propamocarb hydrochloride meets EPA's registration requirements for use on tomato or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of propamocarb hydrochloride by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for propamocarb hydrochloride, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of propamocarb hydrochloride and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of propamocarb hydrochloride in or on tomato and tomato paste at 2 and 5 ppm, respectively ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ($RfD = NOAEL / UF$). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL / \text{exposure}$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve.

To estimate risk, a ratio of the point of departure to exposure ($MOE_{\text{cancer}} = \text{point of departure/exposures}$) is calculated. A

summary of the toxicological endpoints for propamocarb hydrochloride used for

human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PROPAMOCARB HYDROCHLORIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–50 years of age	NOAEL = 150 mg/kg/day UF = 100 Acute RfD = 1.5 mg/kg/day	FQPA SF = 1X aPAD = acute RfD FQPA SF = 1.5 mg/kg/day	Rabbit Developmental LOAEL = 300 mg/kg/day based on increased post-implantation loss
Acute dietary general population including infants and children	NOAEL = 200 mg/kg/day UF = 100 Acute RfD = 2.0 mg/kg/day	FQPA SF = 1X aPAD = acute RfD FQPA SF = 2.0 mg/kg/day	Acute neurotoxicity screening battery-Rat LOAEL = 2,000 mg/kg/day based on decreased body weight gain and decreased motor activity
Chronic dietary all populations	NOAEL = 12 mg/kg/day UF = 100 Chronic RfD = 0.12 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD FQPA SF = 0.12 mg/kg/day	Carcinogenicity study-Mouse LOAEL = 95 mg/kg/day based on decreased body weight and body weight gain in females
Short-term (1 to 7 days) and Intermediate-term (1 week-several months) Dermal (occupational/residential)	Dermal study NOAEL = 150 mg/kg/day	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	21-day dermal toxicity study-Rabbit LOAEL = 525 mg/kg/day based on decreased body weight gain in females
Short-term (1 to 7 days) and Intermediate-term (1 week-several months) Inhalation (occupational/residential)	Inhalation (or oral) study NOAEL = 150 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	Developmental toxicity study-Rabbit Developmental LOAEL = 300 mg/kg/day based on increased post-implantation loss Maternal LOAEL = 300 mg/kg/day based on decreased body weight gain
Cancer (oral, dermal, inhalation)	"Not likely"	Not applicable	Acceptable oral rat and mouse carcinogenicity studies; no evidence of carcinogenic or mutagenic potential

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.499) for the residues of propamocarb hydrochloride, in or on potatoes. Time-limited tolerances for inadvertent residues have been established in or on wheat and wheat by-products. In addition, time-limited tolerances for residues in or on tomato and tomato, paste, and puree have also been established at levels lower than those described in this document. Risk assessments were conducted by EPA to assess dietary exposures from propamocarb hydrochloride in food as follows:

i. *Acute exposure.* Acute dietary 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. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Acute analyses were performed for females 13–50 years old and the general U.S. population (including infants and children); the acute risk was analyzed at the 95th percentile. The aPAD for females 13–50 years old and the general U.S. population (including infants and

children) are 1.5 mg/kg/day and 2.0 mg/kg/day, respectively. For acute dietary risk estimates, EPA's level of concern is >100% aPAD. The results of the acute analysis indicate that the acute dietary risk estimates for the general U.S. population and all population subgroups (at the 95th percentile) associated with the proposed uses of propamocarb hydrochloride do not exceed EPA's level of concern.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A chronic

analysis was performed for the general U.S. population and all population subgroups. The cPAD for the general U.S. population and all subgroups is 0.12 mg/kg/day. For chronic dietary risk estimates, EPA's level of concern is >100% cPAD. The results of the chronic analysis indicate that the chronic dietary risk estimates for the general U.S. population and all population subgroups associated with the proposed uses of propamocarb hydrochloride do not exceed EPA's level of concern.

iii. *Cancer.* There is no concern for mutagenic potential, and there is no evidence of carcinogenic potential in either the rat or mouse. Propamocarb hydrochloride has been classified as "not likely to be carcinogenic in humans." Therefore, a cancer dietary exposure analysis was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for propamocarb hydrochloride in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of propamocarb hydrochloride.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would

ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to propamocarb hydrochloride, they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of propamocarb hydrochloride for acute exposures are estimated to be 1,030 parts per billion (ppb) for surface water and 2.08 ppb for ground water. The EECs for chronic exposures are estimated to be 340 ppb for surface water and 2.08 ppb for ground water.

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).

Propamocarb hydrochloride is currently registered for use on the following residential non-dietary sites: Turfgrass and ornamentals at residential, recreational and golf course sites. However, the usage information in the 1995 Reregistration Eligibility Decision (RED) for propamocarb hydrochloride and the label statement that only protected handlers may be present in the treated area during application, indicate that only commercial applicators will apply the registered end-use product Banol (EPA Registration Number 432-942, contains 66.5% propamocarb hydrochloride) mainly on golf courses and there will be no use on residential or recreational turf. The risk assessment was conducted using the following residential exposure assumptions: An MOE of 100 is adequate to ensure protection from propamocarb hydrochloride via the dermal and inhalation routes for residential exposures. The high-end scenario for residential post-application exposure is the golf course use. The post-application risk assessment is based on generic assumptions as specified by the newly proposed

Residential Standard Operating Procedures (SOPs) and recommended approaches by Health Effects Division's (HED's) Exposure Science Advisory Committee. Short-term post-application exposures are expected for the adult and adolescent golfer. Golfer exposure is expected through minimal hand contact with the golf ball and dermal contact to the lower legs from treated plant surfaces. Since it is assumed that the adolescent golfer would have a proportionally similar exposure to adults, a dermal post-application assessment was performed for the adult golfer only. The calculated MOE for the golfer is 980 and, therefore, does not exceed EPA's level of concern. Since the short- and intermediate-term toxicological endpoints are the same, the golfer post-application exposure assessment is expected to provide adequate exposure estimates for both the short- and intermediate-term. In the event of intermediate-term exposure, propamocarb hydrochloride residues are expected to dissipate over time. Therefore, this assessment is expected to present a high-end conservative estimate of actual exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether propamocarb hydrochloride has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, propamocarb hydrochloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propamocarb hydrochloride has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *Safety factor for infants and children.*—i. *In general.* FFDCA section

408 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity.* There is no evidence of quantitative or qualitative enhanced susceptibility to infants and children. In the rat, developmental effects occur only at doses that cause mortality in the dams. The maternal LOAEL of 740 milligrams active ingredient/kilogram/day (mg a.i./kg/day) is based on mortality. The maternal NOAEL is 221 mg a.i./kg/day. The developmental LOAEL of 740 mg a.i./kg/day is based on increased gestation day (GD) 20 fetal death and a possible increase in minor skeletal anomalies. The developmental NOAEL is 221 mg a.i./kg/day. In the rabbit, developmental effects occur only at doses where there is maternal toxicity. EPA believes that the post implantation loss is actually due to the increased abortions in the does. The maternal LOAEL of 300 mg a.i./kg/day is based on decreased body weight gains for GD 6–18 and possible increased abortions. The maternal NOAEL is 150 mg a.i./kg/day. The developmental LOAEL of 300 mg a.i./kg/day is based on increased post-implantation loss. The developmental NOAEL is 150 mg a.i./kg/day. In the reproduction toxicity study, offspring effects only occurred at levels resulting in maternal toxicity. The LOAEL for systemic/parental toxicity is 8,000 ppm based on decreased body weights of F₀ and F₁ adults. The

systemic/parental toxicity NOAEL is 1,250 ppm.

2. *Conclusion.* There is a complete toxicity data base for propamocarb hydrochloride and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because the prenatal and postnatal toxicology data base is complete and there is no indication of increased susceptibility. A developmental neurotoxicity study is not required. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children from the use of propamocarb hydrochloride.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female),

and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to propamocarb hydrochloride in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of propamocarb hydrochloride on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to propamocarb hydrochloride will occupy 1% of the aPAD for the U.S. population, 1% of the aPAD for females 13 years and older, 3% of the aPAD for all infants (< 1 year old); and 3% of the aPAD for children 1–6 years old. In addition, despite the potential for acute dietary exposure to propamocarb hydrochloride in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of propamocarb hydrochloride in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PROPAMOCARB HYDROCHLORIDE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
All infants (< 1 year old)	2.0	3	1,030	2.08	19,000
Children (1–6 years old)	2.0	3	1,030	2.08	19,000
Females (13–50 years old)	1.5	1	1,030	2.08	45,000
General U.S. population	2.0	1	1,030	2.08	69,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for

chronic exposure, EPA has concluded that exposure to propamocarb

hydrochloride from food will utilize 7% of the cPAD for the U.S. population; 9%

of the cPAD for all infants < 1 year old; and 23% of the cPAD for children 1–6 years old. It has been assumed that there are no residential uses for propamocarb hydrochloride that result in chronic residential exposure to propamocarb hydrochloride. Based on the use pattern,

chronic residential exposure to residues of propamocarb hydrochloride is not expected. In addition, despite the potential for chronic dietary exposure to propamocarb hydrochloride in drinking water, after calculating DWLOCs and comparing them to conservative model

EECs of propamocarb hydrochloride in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PROPAMOCARB HYDROCHLORIDE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.12	7	340	2.08	3,900
Infants (< 1 year old)	0.12	9	340	2.08	1,100
Children (1–6 years old)	0.12	23	340	2.08	920
Females (13–50 years old)	0.12	5	340	2.08	3,400

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Propamocarb hydrochloride is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for propamocarb hydrochloride.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 950, 1,100 and 1,100 for females 13–50 years old, males 13–19 years old and the general U.S. population, respectively. The short-term aggregate risk assessment estimates risks likely to result from 1–7 day exposure to propamocarb hydrochloride residues in food, drinking water, and

residential pesticide uses. High-end estimates of the residential exposure are used in the short-term assessment. Average values are used for food and drinking water exposure.

For short-term aggregate exposure risk, the oral and dermal exposures can be combined since both are based on the same toxicity endpoint (decreased body weight). An MOE of 100 is adequate to ensure protection from propamocarb hydrochloride via the dermal route for residential exposures.

According to the 1995 RED for propamocarb hydrochloride (Estimated Usage of Pesticide, p. 3), “almost all usage of propamocarb hydrochloride in the United States is concentrated on golf courses with approximately 100,000 to 200,000 pounds (lb) active ingredient (ai) applied per year.” The label for Banol states that only protected handlers may be present in the treated area during application. For these

reasons, it is assumed that this product will be used by commercial applicators, mainly on golf courses. The high-end scenario for residential post-application exposure is the golf course use of Banol. Therefore, in aggregating short-term risk, the Agency considered background chronic dietary exposure (food and drinking water) and short-term golfer dermal exposure. These aggregate MOEs do not exceed the Agency’s level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of propamocarb hydrochloride in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency’s level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PROPAMOCARB HYDROCHLORIDE

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Females (13–50 years old)	950	100	1,030	2.08	40,000
Males (13–19 years old)	1,100	100	1,030	2.08	63,000
General U.S. population	1,100	100	1,030	2.08	63,000

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). The short-term aggregate assessment adequately addresses both the short- and intermediate-term golfer dermal

exposures. The short- and intermediate-term dermal endpoints were chosen from the 21-day dermal rabbit toxicity study. The short-term golfer exposure was calculated assuming 1–7 day exposure to propamocarb hydrochloride. The intermediate-term aggregate risk assessment estimates risks likely to result from 7 days to 3 months

exposure. In the event of intermediate-term exposure, propamocarb hydrochloride residues are expected to dissipate over time. Therefore, the short-term aggregate assessment is expected to present a high-end conservative estimate of intermediate-term risk. As the short-term aggregate risk assessment represents the high-end scenario, an

intermediate-term assessment was not performed.

5. *Aggregate cancer risk for U.S. population.* An aggregate cancer risk analysis was not performed since there is no concern for mutagenic potential and there is no evidence of carcinogenic potential in either the rat or mouse. Propamocarb has been classified as "not likely to be carcinogenic in 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, and to infants and children from aggregate exposure to propamocarb hydrochloride residues.

V. Other Considerations

A. Analytical Enforcement Methodology

A gas chromatography method was utilized for the determination of propamocarb hydrochloride residues in/on raw agricultural commodity samples collected from the potato field study and field rotational crop study. The reported limit of quantitation was 0.05 ppm. The method validation and concurrent method recovery data indicate that this method is adequate to support the time-limited tolerances associated with this action. An identical method is proposed for tolerance assessment. The proposed method has undergone a successful independent lab validation and petition validation method. EPA concludes that the requirements for a plant enforcement method have been fulfilled.

A ruminant feeding study is required. Conclusions about the need for livestock tolerances and appropriate enforcement analytical method are deferred until receipt of the ruminant feeding study and determination of the residues of concern in livestock.

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

B. International Residue Limits

A CODEX MRL of 1 mg/kg has been established for residues of propamocarb per se in/on tomatoes. The use pattern used for determining the CODEX MRL differs from that in this section 18 exemption (maximum use rate overseas is 3.2 lb a.i./acre per application, the maximum use rate in the United States is 0.9 lb a.i./acre. No Canadian or Mexican residue limits have been established.

C. Conditions

The conditions of registration will include submission of a livestock feeding study (which determines the metabolites N-oxide propamocarb, 2-hydroxy propamocarb and oxazolidine) and storage stability data from the livestock feeding study. The need for a livestock analytical enforcement method and livestock tolerances will be determined after receipt of the ruminant feeding study and determination of the residues of concern in livestock. A corrosion characteristics study must be submitted as soon as completed.

VI. Conclusion

Therefore, the tolerances are revised for residues of propamocarb hydrochloride, propyl [3-(dimethylamino)propyl]carbamate monohydrochloride, in or on tomato and tomato, paste at 2 and 5 ppm, respectively. In addition, the tolerance for residues of propamocarb hydrochloride in or on tomato puree is hereby revoked.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301162 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 November 20, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in

the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP-301162, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule revises and revokes time-limited tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44

U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175,

entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.”

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 10, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. In § 180.499, the table in paragraph (b) is amended by revising the entry for Tomato, paste, by removing the entries for Tomato, puree and Tomatoes, and by adding an entry for Tomato to read as follows:

§ 180.499 Propamocarb hydrochloride; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* *	* *	* *
Tomato	2.0	12/31/03
Tomato, paste	5.0	12/31/03
* *	* *	* *

* * * * *

[FR Doc. 01-23608 Filed 9-20-01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301174; FRL-6803-1]

RIN 2070-AB78

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of azoxystrobin in or on acerola, atemoya, avocado, biriba, black sapote, leafy greens (Brassica) subgroup (subgroup 5B), bushberry subgroup (subgroup 13B), canistel, cherimoya, custard apple, eggplant, feijoa, grass forage, grass hay, guava, ilama, jaboticaba, jackfruit, juneberry, lingonberry, longan, loquat, lychee, mamey sapote, mango, okra, passion fruit, pawpaw, papaya, pepper, peppermint (tops), persimmon, pulasan, rambutan, salal, sapodilla, soursop, Spanish lime, spearmint (tops), star apple, starfruit, strawberry, sugar apple, tamarind, turnip (tops), watercress, wax jambu, and white sapote. The Interregional Research Project #4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. This final rule establishes permanent tolerances for azoxystrobin, and as part of that process the Agency has reassessed existing tolerances. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. All permanent tolerances for azoxystrobin were established after

August 2, 1996. Consequently, regarding the actions in this final rule, no tolerance reassessments are counted toward the August 2002 review deadline of FFDCA section 408(q).

DATES: This regulation is effective September 21, 2001. Objections and requests for hearings, identified by docket control number OPP-301174, must be received by EPA on or before November 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301174 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9368; and e-mail address: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111	Crop production Animal production Food manufacturing Pesticide manufacturing
	112	
	311	
	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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person

listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301174. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of May 30, 2001 (66 FR 29317) (FRL-6782-2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of pesticide petitions (PP) for tolerances by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. This notice included a summary of the petitions prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.