adversely effect the endocrine system (i.e. chlorine and other reactant species).

C. Aggregate Exposure

1. *Dietary exposure*. The proposed use of sodium thiosulfate as an adjuvant (1 tablet to 100 gallons of water or up to 14 oz. of end product containing 1–6% sodium thiosulfate to 100 gallons of water) to remove chlorine and other reactive species from tank water ensures that there is no dietary exposure to sodium thiosulfate. Due to the breakdown of sodium thiosulfate in water to sodium chloride, water, sulfur and sulfate, there are no residues of sodium thiosulfate applied to the plants and thus there are no residues in food.

i. *Food*. The proposed use will not result in any dietary exposure beyond what is currently present in salt and alcohol.

ii. *Drinking water*. There is no exposure to sodium thiosulfate through drinking water. Any sodium thiosulfate that gets into water is quickly broken down to the following non-toxic compounds: sodium chloride, water, sulfur and sulfate.

2. *Non-dietary exposure*. The only anticipated human exposure to non-dietary sources of sodium thiosulfate would be through medical treatment, occupational exposure, or aquaculture (hobbyists).

D. Cumulative Effects

Studies have shown that excess sodium thiosulfate beyond endogenous levels of thiosulfate is rapidly cleared from the body and there are no cumulative effects. It should also be noted that with the exception of possible occupational exposure of the mixer/loader/applicator, the proposed uses of sodium thiosulfate will not result in exposure to any other person or any non-target organism.

E. Safety Determination

1. *U.S. population*. The use of sodium thiosulfate as an adjuvant added to tank mixes does not pose a safety concern for the U.S. population due to the non-toxic nature of the compound and the absence of exposure.

2. *Infants and children*. Infants and children will not be exposed to sodium thiosulfate from its use as an adjuvant in conjunction with formulated products.

F. International Tolerances

There are no known international tolerances for sodium thiosulfate.

[FR Doc. 00–22390 Filed 9–5–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–975; FRL–6743–6]

Notice of Filing Pesticide Petitions to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–975, must be received on or before October 6, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–975 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dani Daniel, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5409; e-mail address: daniel.dani@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	111 112 311 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/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–975. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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 Highway, 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–975 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records

Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–975. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 25, 2000.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner summary of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summary of the petitions was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summaries announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Novartis Crop Protection, Inc.

PP 9F5046 and PP 9F5051

EPA has received amended pesticide petitions (PP 9F5046 and PP 9F5051) from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for the combined residues of thiamethoxam, 3-[(2-chloro-5-thiazolyl) methyl] tetrahydro-5-methyl-*N*-nitro-4H-1, 3, 5-oxadiazin-4-imine and its major metabolite CGA–322704 *N*-(2-chloro-thiazol-5-ylmethyl)-*N'*-methyl-*N''*-nitro-guanidine which will be commonly referred to as thiamethoxam throughout the rest of this document in or on the raw agricultural commodity rapeseed (canola), tuberous and corm vegetables crop subgroup, barley grain, sorghum grain, sorghum forage, sorghum stover, wheat grain, wheat hay, wheat straw, and milk at 0.02 parts per million (ppm); barley straw at 0.03 ppm; barley hay at 0.05 ppm; cotton, undelinted seed at 0.10 ppm; cucurbit vegetables crop group, and pome fruit crop group at 0.20 ppm; fruiting vegetables crop group at 0.25 ppm; wheat forage at 0.50 ppm; tomato paste at 0.80 ppm; head and stem Brassica vegetables crop subgroup at 1.00 ppm; cotton gin byproducts at 1.50 ppm; leafy vegetables crop group, and leafy Brassica greens crop subgroup at 2.00 parts per million (ppm). In addition, meat of cattle, goats, horses, and sheep at 0.02 ppm and meat byproducts of cattle, goats, horses, and sheep at 0.02 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

The residue chemistry profile for thiamethoxam which supports these amended petitions for tolerances was previously published in the **Federal Register** of May 5, 1999 (64 FR 24153) (FRL–6072–7).

B. Toxicological Profile

The toxicological profile for thiamethoxam which supports these amended petitions for tolerances was previously published in the **Federal Register** of May 5, 1999 (64 FR 24153).

C. Aggregate Exposure

1. *Dietary exposure.— Food and drinking water.* Chronic dietary exposure was estimated using a Tier I approach by inputting tolerance level residues into the dietary exposure evaluation model (DEEM™) software. The Tier I assessment was partially refined by adjusting for projected percent crop-treated information, and was made using the United States Department of Agriculture (USDA) national food consumption survey, continuing survey of food intakes by individuals (CSFII) 1994–96. The maximum total exposure to the U.S. population (48 contiguous states, all seasons) was calculated to be 4.1% of the reference dose (RfD) of 0.013 milligrams/kilograms (mg/kg) body weight/day (bwt/day). The maximum exposure to the most sensitive population subgroup, children (1–6 years) was 9.5% of the RfD. The inclusion of the maximum concentration (Cmax) of thiamethoxam in water, taken from the highest estimated concentration observed from the generic expected environmental concentration (GENEEC) and screening concentration in ground water (SCI GROW) models, led to a maximum chronic dietary exposure of 4.5% in the U.S. population and 10.0% in children (1–6 years old).

Acute dietary exposure was calculated using a Tier III, probabilistic assessment. A distribution of residue data points was included for the typically non-blended commodities of vegetables (tuberous, fruiting, cucurbit, Brassica, and leafy), pome fruits, meat and milk, while the average field trial value was used for the typically blended commodities of grains (wheat, sorghum, and barley), seed oil (cotton and canola), apple juice and tomato paste and puree. The acute assessment used adjustment for percent of crop treated, and was made using the DEEM software with the Monte Carlo analysis and the CSFII 1994–96 food consumption survey. The margin of exposure (MOE) no observed adverse effect level ((NOAEL)/exposure) for the U.S. population (all seasons) at the 99.9th percentile of the exposure distribution was 4,995 using the NOAEL value of 15 mg/kg bwt/day. At the 99.9th percentile, the MOE for the most sensitive population subgroup (non-nursing infants <1 year old) was 1,012. Inclusion of the drinking water value to the acute assessment led to an MOE of 4,904 at the 99.9th percentile of the U.S. population, and 1,008 for the population subgroup non-nursing infants <1 year old. The results of these analyses show that there is reasonable certainty that no harm will result from exposure to dietary residues (including drinking water) of thiamethoxam.

2. *Non-dietary exposure.* Novartis also requests registrations for the use of thiamethoxam on dogs, turf and ornamentals. Novartis has identified potential non-dietary exposures to toddlers for these uses. These exposures include the following scenarios: Incidental non-dietary ingestion of residues on lawns from hand-to-mouth transfer, ingestion of thiamethoxam treated grass, and incidental ingestion of pesticide residues on pets from hand-to-mouth transfer.

According to current EPA policy, these exposures are considered to be short-term oral exposures. EPA does not expect incidental ingestion of pesticide residues on pets from hand-to-mouth transfer to occur during the same period as the exposures from the turf uses. Thus, Novartis considered these exposures in separate estimates of risk. According to current EPA policy, if an oral endpoint is needed for short-term risk assessment (for incorporation of food, water, or oral hand-to-mouth type exposures into an aggregate risk assessment), the acute oral endpoint (acute RfD = 15 mg/kg bwt/day) will be used to incorporate the oral component into aggregate risk. Short-term aggregate exposure is defined by EPA to be average food and water exposure (chronic exposure) plus residential exposure. The short-term risk estimates for the population subgroup children, 1 to 6 years old, is summarized below. This population subgroup was chosen because it has the highest chronic food exposure and because toddlers have the highest exposure from the residential uses. From the results below, Novartis concludes there is no concern associated with the aggregate exposure to thiamethoxam: Short-term aggregate exposure and risk including turf for children 1 to 6 years old; dietary exposure estimate including water is 0.001296 mg/kg bwt/day; residential exposure from turf is calculated to be 0.00497 mg/kg bwt/day; total exposure equals 0.0063 mg/kg bwt/day; percent acute RfD consumed is 0.04%; short-term aggregate exposure and risk including pet use for children 1 to 6 years old; dietary exposure estimate including water is 0.001296 mg/kg bwt/day; predicted hand to mouth transfer is 0.0341 mg/kg bwt/day; total exposure equals 0.035 mg/kg bwt/day; and the percent acute RfD consumed is 0.23%

D. Cumulative Effects

The potential for cumulative effects of thiamethoxam and other substances that have a common mechanism of toxicity has also been considered. Thiamethoxam belongs to a new pesticide chemical class known as the neonicotinoids. There is no reliable information to indicate that toxic effects produced by thiamethoxam would be cumulative with those of any other chemical including another pesticide. Therefore, Novartis believes it is appropriate to consider only the potential risks of thiamethoxam in an aggregate risk assessment.

E. Safety Determination

1. *U.S. population.* Using the chronic exposure assumptions and the proposed RfD described above, the aggregate exposure (including drinking water) to thiamethoxam to the U.S. population (48 contiguous states, all seasons) was calculated to be 4.5% of the reference dose of 0.013 mg/kg bwt/day. Therefore, Novartis concludes that there is reasonable certainty that no harm will result from aggregate chronic exposure to thiamethoxam residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of thiamethoxam, data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat have been considered.

In teratology studies, delayed fetal development was apparent only at maternally toxic doses of thiamethoxam in rats and rabbits. In rabbits, 150 mg/kg/day was clearly toxic to does, causing death, weight loss, reduced food consumption, and perineal or vaginal discharge. Developmental toxicity occurred secondary to maternal toxicity and consisted of reduced fetal body weights and an increase in minor skeletal anomalies or variations. Maternal toxicity was also noted at 50 mg/kg/day, consisting of reduced body weight and food consumption and total resorptions in one female. There was no indication of developmental toxicity at 50 mg/kg/day.

The NOAEL for maternal toxicity was 15 mg/kg/day and for developmental toxicity was 50 mg/kg/day in rabbits. In rats, 200 and 750 mg/kg/day caused maternal toxicity, but developmental toxicity secondary to maternal toxicity was observed only at 750 mg/kg/day. The NOAEL for maternal toxicity was 30 mg/kg/day and for developmental toxicity was 200 mg/kg/day.

In a rat multi-generation study, parental toxic effects were noted at 2,500 ppm (250 mg/kg/day) and 1,000 ppm (100 mg/kg/day). Offspring body weights were reduced in males and females at 2,500 ppm (250 mg/kg/day) and in females (F1 only) at 1,000 ppm (100 mg/kg/day). The NOAEL for

systemic toxicity in adult males was 30 ppm (approximately 3 mg/kg/day, range = 1.3 – 4.3 mg/kg/day) and in adult females was 1,000 ppm (approximately 100 mg/kg/day, range = 59.3 – 219.6 mg/kg/day). The NOAEL for toxicity to offspring was 30 ppm (approximately 3 mg/kg/day, range = 1.3 – 6.4 mg/kg/day). These studies show no evidence that developing offspring are more sensitive to than adults to the effects of thiamethoxam.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological requirements, the data base for thiamethoxam relative to prenatal and postnatal effects for children is complete. Further, for thiamethoxam, the developmental studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, and no increased sensitivity in pups as compared to the adults in the multi-generation reproductive toxicity study. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that an RfD of 0.013 mg/kg/day is appropriate for assessing aggregate risk to infants and children of thiamethoxam.

Assuming tolerance level residues and adjusting for the percent of crops treated, only 7.0% of the thiamethoxam chronic RfD is utilized in the population subgroup all infant (<1 year old). Therefore, based on the completeness and reliability of the toxicity data base, Novartis concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to thiamethoxam residues.

F. International Tolerances

There are no Codex, Canadian, or Mexican maximum residue levels established for the combined residues of thiamethoxam on rapeseed (canola), fruiting vegetables, tomato paste, head and stem Brassica vegetables, leafy Brassica greens, cucurbit vegetables, leafy vegetables, tuberous, and corm vegetables, barley grain, barley hay, barley straw, cotton (undelinted seed), cotton gin byproducts, pome fruit, wheat grain, wheat forage, wheat straw, wheat hay, sorghum grain, sorghum forage, sorghum stover, meat, and meat byproducts of cattle, goats, horses, and sheep, and milk.

[FR Doc. 00–22391 Filed 9–5–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–968; FRL–6739–7]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–968, must be received on or before October 6, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–968 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6379; e-mail address: gairola.indira@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	111 112 311 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/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–968. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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 Highway, 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is