

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-969; FRL-6738-4]

**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-969, 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-969 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/fedrgrstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-969. 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-969 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](mailto: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-969. 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 a pesticide petition 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 Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition 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 23, 2000.

**Peter Caulkins, Acting**

Director, Registration Division, Office of Pesticide Programs.

### Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary 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.

## Eden Bioscience Corporation

PP OE6177

EPA has received a pesticide petition (PP OE6177) from Eden Bioscience Corporation, 11816 North Creek Parkway N., Bothell WA 98011-8205] proposing, pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the inert ingredient sodium thiosulfate when used as a dechlorinator in pesticide formulations for protein based products when applied to growing crops or to raw agricultural commodities after harvest. 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

### A. Residue Chemistry

1. *Plant metabolism.* Due to the breakdown of sodium thiosulfate in chlorinated water to sodium chloride, water, sulfur, and sulfate prior to application to plants, there is no plant metabolism of the parent compound. All of the breakdown products are considered to be plant nutrients. Sodium thiosulfate pentahydrate (CAS 10102-17-7) is an odorless crystalline substance with a molecular weight of 248.18. The molecular formula is  $\text{Na}_2\text{S}_2\text{O}_3$  (Na 29.08%, O 30.36%, S 40.56%). It has a pKa of 1.6, is soluble in water (42%; by weight at 0°C) and insoluble in alcohol. The aqueous solution is practically neutral with a pH range of 6.5–8.0. In aqueous solution sodium thiosulfate slowly decomposes to its molecular constituents. Sodium thiosulfate pentahydrate has a melting point of 48°C when heated rapidly. It loses all its water at 100°C and decomposes at higher temperatures. When sodium thiosulfate is used to remove chlorine from an aqueous solution it follows the equations:  $\text{Na}_2\text{S}_2\text{O}_3 + 4\text{Cl}_2 + 5\text{H}_2\text{O} = 2\text{NaHSO}_4 + 8\text{HCl}$  and  $\text{Na}_2\text{S}_2\text{O}_3 + 2\text{HCl} = 2\text{NaCl} + \text{H}_2\text{O} + \text{S} + \text{SO}_2$ .

2. *Analytical method.* Analysis of sodium thiosulfate can be accomplished through a variety of methods. Some researchers have employed a gas chromatographic (GC) analytical method using a C18 column and 420-E fluorescence detector for determining elution of thiosulfate in plasma and urine. Other researchers have reported using a high performance liquid chromatographic (HPLC) method used

to determine thiosulfate plasma and urine. Medical researchers have also described the use of a clinical nephelometer to determine sulfate and thiosulfate concentrations in plasma and urine.

3. *Magnitude of residues.* 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.

### B. Toxicological Profile

Sodium thiosulfate is considered to have low toxicity and has been safely used for over 100 years as a therapeutic agent. Medical uses of sodium thiosulfate have been well documented since 1895. In humans it is employed as an antidote for acute cyanide poisoning; as a chemoprotectant against carboplatin and cisplatin induced ototoxicity; to prevent cyanide poisoning from treatment with sodium nitroprusside, nitrile compounds and laetrile; to reduce calcinosis; and is used topically to treat acne and pityriasis versicolor (tinea versicolor, a type of ringworm). Recent studies have shown that sodium thiosulfate may be effective in reducing some chemically induced cancers. In veterinary medicine it is used: to treat or prevent cyanide poisoning; as a "general detoxifier" to treat bloat; and when applied dermally to treat ringworm and mange. Sodium thiosulfate is also being used experimentally to increase food utilization in livestock.

Sodium thiosulfate is used to treat drinking water where there is concern with high levels of chlorine, chloroform or other reactive species, especially in drinking water produced by desalination plants. It is also used as a dechlorinator in aquariums and aquaculture, and in a number of manufacturing processes that require the removal of chlorine or other reactive species.

Sodium thiosulfate is classified in the Code of Federal Regulations, U.S. Food and Drug Administration, title 21, part 184, as a Direct Food Substance Affirmed As Generally Recognized As Safe (Section 184.1807) and title 21, part 582 as a Substance Generally Recognized As Safe, (Section 582.6807). According to section 184.1807, sodium thiosulfate is used as a formulation aid and a reducing agent. It is used in alcoholic beverages and table salt at levels not to exceed good manufacturing practice, currently 0.00005 percent in alcoholic beverages and 0.1% in table salt. Section 582.6807 authorizes the use of sodium thiosulfate as a sequestrant in salt with a tolerance of 0.1%.

1. *Acute toxicity.* Sodium thiosulfate is not well absorbed through the intestinal tract at high doses. Sodium thiosulfate is low in acute toxicity but may cause irritation of the gastrointestinal tract and purging if large quantities are ingested. Doses of 8 g/kg in rats are reported to be non-toxic upon ingestion.

Sodium thiosulfate has been used as a topical treatment for a variety of ailments for numerous years. Sodium thiosulfate is available in various lotion formulations such as Komed™, an acne medication containing 8% sodium thiosulfate together with 2% salicylic acid, 25% isopropyl alcohol and other ingredients. Tinver™ and Versiclear™, are lotions used for tinea versicolor (ringworm). Both lotions contain 25% sodium thiosulfate, 1% salicylic acid and 10% isopropyl alcohol. It is recommended that the lotions be applied twice daily to affected and susceptible skin for at least a week to many months until complete control of tinea versicolor is achieved. Sodium thiosulfate (12%) is also mixed with a sterile solution of 0.5% potassium ferricyanide to treat silver nitrate burns. No adverse effects are expected when sodium thiosulfate is used topically.

There is little information available on inhalation toxicity of sodium thiosulfate, but as with all dust or crystalline compounds, breathing product dust or mist may irritate the respiratory tract. However, sodium thiosulfate will be compressed into tablets for ease of use, thus eliminating the hazard of dust inhalation. Product labeling calls for mixers to wear a dust mask, thus precluding inhalation of dust when sodium thiosulfate is present as part of the product formulation.

The use of sodium thiosulfate as an adjuvant is not expected to pose an inhalation hazard since it will be in tablet form or is already incorporated into the formulation at low concentrations (one to six%). Once the sodium thiosulfate either in tablet form or in the formulated end product is mixed with water, it breaks down into sodium chloride, water, sulfur and sulfate, which eliminates further possibility of inhalation exposure from the parent compound.

Although intravenous (IV) exposure to sodium thiosulfate is irrelevant to concerns with its use as an adjuvant, information from IV studies and therapeutic uses provides further data on the safety of sodium thiosulfate.

Sodium thiosulfate is considered to be essentially a nontoxic drug, although nausea and vomiting have been described with rapid IV administration of antidotal doses to normal adult

human volunteers. The standard dose of sodium thiosulfate for treatment of cyanide poisoning in humans is an IV administration of 50 mL of a 250 milligrams/mL (mg/mL) (25%) solution. Patients also have been administered 50 mL of a 50% sodium thiosulfate solution without adverse effects.

Sodium thiosulfate administered IV at 150–200 milligrams/kilograms (mg/kg) over a period of 15 minutes, is part of the therapy to treat suspected cyanide toxicity from administration of sodium nitroprusside.

The lethal dose of sodium thiosulfate when given at intravenous doses to rats is greater than 2.5 g/kg. The IV LD<sub>50</sub> in mice is 1.19 g/kg, while the median lethal dose in dogs is 3 g/kg. The lethal dose injected into the flank of rabbits was estimated to be 4 g/kg. The main toxic effects from IV administration of sodium thiosulfate appear to be osmotic, which result from the rapid sodium load together with acid-base disturbances. Osmotic and acid-base disturbances have not been observed at lower doses or from dermal or oral administration of sodium thiosulfate.

Information from intraperitoneal (IP) studies provide further support that sodium thiosulfate has relatively low acute toxicity. Sodium thiosulfate protects the auditory system from the major ototoxic effects of cisplatin and reduces other overt signs of systemic toxicity.

Hamsters receiving IP injections of sodium thiosulfate at 1,600 mg/kg every other day until five injections were completed showed no ill effects from sodium thiosulfate. When sodium thiosulfate was injected in hamsters in combination with cisplatin (a chemotherapeutic agent that has been shown to cause ototoxicity), sodium thiosulfate provided amelioration over a broad hearing range, as well as providing protection from cisplatin induced gastrointestinal necrosis and nephrotoxicity. Similarly, in a study where guinea pigs treated with cisplatin, cisplatin and sodium thiosulfate, saline or sodium thiosulfate only (1,600 mg/kg/day for eight days), there were no signs of toxicity in any of the guinea pigs treated with sodium thiosulfate only. There were no effects on body weight (bwt) or auditory brainstem response and animals treated with cisplatin and sodium thiosulfate, had improved hearing and lost less weight than animals treated with cisplatin only.

Sodium thiosulfate has been shown to be an effective antidote in mice exposed to acrylonitrile. Mice were given IP injections of sodium thiosulfate at 400 mg/kg from 10 to 30 minutes prior to

acrylonitrile administration at the LD<sub>50</sub> dose level of 60 mg/kg. All mice appeared normal after prophylactic treatment with sodium thiosulfate and showed no ill effects from subsequent acrylonitrile exposure. Animals treated with sodium thiosulfate only, showed no evidence of toxicity.

Aquated cisplatin has a higher uptake by tumors than that of cisplatin, but aquated cisplatin is also more nephrotoxic. Subcutaneous injection of sodium thiosulfate (1,000 mg/kg) five minutes before IP administration of aquated cisplatin to B6D2F1 mice resulted in reduced aquated cisplatin-induced nephrotoxicity.

2. *Genotoxicity.* Sodium thiosulfate is not genotoxic and is regularly used in cell culture mediums as a source of sulfur. Sodium thiosulfate does not cause cell death or reduce the rate of growth in a wide variety of bacteria. Sodium thiosulfate is non-mutagenic to *Salmonella typhimurium* and can reduce the mutagenic effects induced by other chemicals. Sodium thiosulfate does not increase the rate of sister chromatid exchanges (SCEs) or chromosomal aberrations in human lymphocytes. Sodium thiosulfate has been shown to reduce the number of SCEs in human lymphocytes and Chinese hamster (CH) lung cells when administered simultaneously with known SCE inducers. When sodium thiosulfate at concentrations up to 5 X 10<sup>2</sup> M was added to untreated human cells, there was no effect at all on the cells. *In vitro* studies with sodium thiosulfate and LX-1 small-cell lung carcinoma cells found that sodium thiosulfate concentrations of 10 mg/kg and above were toxic to LX-1 cells, presumably due to high osmolarity, however, lower concentrations of sodium thiosulfate had no effect on cell growth. Sodium thiosulfate has also been shown to inhibit cisplatin-induced mutagenesis in somatic tissue of *Drosophila*.

3. *Reproductive and developmental toxicity.* Sodium thiosulfate is not considered to be a reproductive or developmental toxicant due to its rapid breakdown in the body to normal constituents, (i.e. thiosulfate is a normal constituent of blood and is utilized by mitochondrial enzyme rhodanase, a.k.a. thiosulfate sulfurtransferase, as a sulfur donor). In addition, remaining thiosulfate is rapidly hydrolyzed by water into sodium chloride, water, sulfur and sulfate, which are all compounds readily used by living organisms.

Use of sodium nitroprusside for the treatment of hypertensive emergencies in pregnancy has been hampered by

concern for the possibility of cyanide poisoning in both the mother and fetus. Coinfusion of sodium thiosulfate with nitroprusside in gravid ewes prevented fetal and maternal cyanide toxicity. Physicians are currently treating some pregnant women with IV administration of sodium thiosulfate and sodium nitroprusside.

4. *Subchronic toxicity.* No studies that fall into the usual subchronic category were found. However, data from chronic and acute studies provides adequate information as to the non-toxicity of sodium thiosulfate. However, it should be noted that Versiclear™, Lotion containing 25% sodium thiosulfate and 1% salicylic acid in propylene glycol is recommended for subchronic treatment of tinea versicolor in humans. In a series of studies of various therapeutics for cyanide poisoning in sheep, up to 660 mg/kg of sodium thiosulfate was administered in distilled water via stomach tube directly to the rumen of ewes who had been treated with lethal doses of sodium cyanide (7.6 mg/kg). All ewes treated with 660 mg/kg sodium thiosulfate survived. Ewes receiving 66.7 mg/kg sodium thiosulfate still exhibited severe signs of cyanide poisoning and subsequently died. Based on this study, it is recommended that cyanide toxicity in ruminants should be treated with high doses of sodium thiosulfate (500 mg/kg or more) and repeated as needed, since sodium thiosulfate is rapidly cleared from the body and sustained release of free cyanide from the rumen is possible.

An evaluation of 41 potential chemopreventive agents using the inhibition of carcinogen-induced aberrant crypt foci (ACF) in the rat colon as the measure of efficacy found that sodium thiosulfate was one of 18 agents that significantly reduced the incidence of ACF.

5. *Chronic toxicity.* Long term treatment of patients with a variety of illness have shown that ingestion of low levels of sodium thiosulfate is a non-toxic and safe therapeutic agent. A patient with renal tubular acidosis 1 was treated for nine years with sodium thiosulfate, 15–20 mmol daily (orally), to control nephrocalcinosis. During this time period, there were no treatment-related adverse effects, nephrocalcinosis did not worsen, and renal function improved. Thirty four patients received daily oral doses of sodium thiosulfate (10 mmol twice daily with p=meals) for three to four years in the treatment of recurrent calcium urinary lithiasis. Sodium thiosulfate was well tolerated by all patients for over four years with no apparent toxic or side effects. It was also found that the patients only

absorbed 20–25% of the oral dose, excreting four to five mmol as urinary thiosulfate. Higher oral dose levels of sodium thiosulfate resulted in watery stools in some patients so was not used in this clinical trial.

Three patients undergoing maintenance hemodialysis for more than four years developed calcified masses. To reduce the symptoms, each patient was given 20 mmol of sodium thiosulfate IV at the end of each hemodialysis for the next six to 12 months. A considerable regression of calcified masses with concurrent clinical improvement was observed in two of the patients while the third patient showed a softening in the mass but no regression in size due to encapsulation prior to starting sodium thiosulfate treatment. For all patients, there were no new calcified masses observed during sodium thiosulfate treatment, sodium thiosulfate was well tolerated, and no apparent side effects were observed.

6. *Animal metabolism.* Thiosulfate is a normal constituent of mammalian urine. In humans, urinary thiosulfate excretion averages approximately 30  $\mu$ mol per 24 hours, which is less than 1% of the total urinary sulfur load.

Sodium thiosulfate is not well absorbed when administered orally as it is broken down in the acidic gastric juices to form sulfite and sulphur. Research has shown that 20–25% of a chronic low level dose is excreted in the urine as urinary thiosulfate.

When sodium thiosulfate is given intravenously, it is distributed throughout the extracellular fluid and renal excretion occurs by glomerular filtration and secretion. The serum half-life of thiosulfate in humans (after bolus injections) is around 15 to 20 minutes. When sodium thiosulfate is administered during sodium nitroprusside therapy, the plasma half life of thiosulfate is reported to be as short as 15 minutes to as long as three hours. Depending on the dosage, around 10 to 50% of exogenous thiosulfate is eliminated unchanged via the kidneys.

Endogenous levels of plasma and urinary thiosulfate concentrations, determined from healthy volunteers are  $1.13 \pm 0.11$  milligrams/dL (mg/dL) and  $0.28 \pm 0.02$  mg/dL, respectively. Clearance of endogenous thiosulfate in normal males was  $0.26 \pm 0.04$  mL/min, with net excretion accounting for only 0.17% of the filtered load. The majority of endogenous thiosulfate is actively reabsorbed and endogenous levels are regulated by the kidney through secretion into and reabsorption out of tubules.

Sodium thiosulfate is known to be a strong diuretic. Following IV administration of sodium thiosulfate, peak thiosulfate concentrations were obtained five minutes after injection. The half life of the distribution phase was 23 minutes while that of the elimination phase was 182 minutes. Urine concentration, clearance and rate of thiosulfate excretion increased markedly after injection. Total excretion was  $42.6 \pm 3.5\%$  of the injected dose at 180 min. Total excretion increased to only  $47.4 \pm 2.4\%$  at 18 hours after injection. Sodium thiosulfate kinetics were also studied in patients undergoing cancer treatment. Sodium thiosulfate was eliminated from the plasma by first-order kinetics. On the average approximately 28% of the dose was recovered unchanged in the urine. In these patients, 95% of the total recoverable thiosulfate was excreted within four hours after termination of infusion. When sodium thiosulfate is coadministered with cisplatin (a chemotherapeutic agent that often causes nephrotoxicity), inactive mobile metabolites of cisplatin are formed by a direct reaction between cisplatin and sodium thiosulfate in the systemic circulation, which results in a reduction in the amount of cisplatin in the kidney. The strong diuretic action of sodium thiosulfate also increases elimination of both compounds, thus minimizing the time the remaining cisplatin is in the kidneys.

Sodium thiosulfate has been used to estimate extracellular water in cattle and was found to reach equilibrium with extracellular water in five to ten minutes after infusion. Sodium thiosulfate was cleared from venous blood in a two part fashion: first, it was cleared from the plasma into the interstitial fluid, then secondly through renal clearance from the extracellular water. A first-order clearance of the sodium thiosulfate was demonstrated 15 to 20 minutes after infusion. When combined with urea, sodium thiosulfate gave reasonable estimates of empty body water, extracellular water, intracellular water and lean body mass. No adverse effects were noted in any of the steers.

7. *Metabolite toxicology.* None of the metabolites of sodium thiosulfate are considered to be of toxicological significance. Thiosulfate is a normal body constituent as are the other breakdown products from the reaction of sodium thiosulfate in chlorinated water: sodium chloride, water, sulfur and sulfate.

8. *Endocrine disruption.* Sodium thiosulfate does not effect the endocrine system, except as a detoxifying agent of compounds that have been shown to

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
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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.**

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