ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0352; FRL–7336–4]

Cis-Isomer of 1-(3-Chloroallyl)-3,5,7-Triaza-1-Azoniaadamantane Chloride; 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 identification (ID) number OPP–2003–0352, must be received on or before January 16, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0371; e-mail address: *parker.james@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0352. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA's Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk

or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0352. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2003–0352. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0352.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0352. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 ID 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 FFDCA 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: Decembern 4, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. 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.

Dow Chemical Company

PP 3E6656

EPA has received a pesticide petition (3E6656) from Dow Chemical Company, Building 1803, Midland, Michigan 48674, 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 cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CAS Reg. No. 51229–78–8), when used as an inert ingredient, a preservative in pesticide formulations applied to growing crops. 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*. Residue chemistry data are not generally required by EPA regarding tolerance exemption petitions. Consequently, no plant metabolism data have been generated.

2. *Analytical method*. Since this petition is for an exemption from the requirement of a tolerance, an enforcement analytical method for cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is not needed.

3. *Magnitude of residues*. Based on the negligible amount of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride to be used in final product formulations (0.14% by weight (wt) or less), the recommended frequency and rates of application to growing crops, and the hydrolysis characteristics of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride with the rapid degradation action of formaldehyde, the Dow Chemical Company believes that residues are expected to be essentially undetectable and not toxicologically significant.

B. Toxicological Profile

In the Dowicil CTAC Reregistration Eligibility Document (RED), dated April 1995, EPA completed it's assessment of the potential human health and environmental risks associated with the active ingredient non-food uses of the cis and trans isomer mixture of 1-(3-chlorallyl)-3,5,7-triaza-1-azoniaadamantane chloride and the cis-isomer of 1-(3-chlorallyl)-3,5,7-triaza-1-azoniaadamantane chloride. Due to the similarities of the two active ingredients the Agency accepted toxicology studies conducted using either the cis and trans isomer mixture or the cis isomer only. Thus, the existing data base includes toxicity studies that were performed with the cis-isomer and the toxicity studies that were performed with a mixture of the cis and trans isomers.

1. *Acute toxicity*—i. *Acute oral*. Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was administered by single-dose gavage to 6 groups of 6 rats/sex/dose at dosages of 200, 400, 800, 1,600, 3,200, and 6,300 milligrams/kilogram (mg/kg). Clinical signs of lethargy, diarrhea, and lacrimation, were observed at the 800, 1,600, and 3,200 mg/kg dose groups. Body tremors and exudate staining of the nares were also seen in the 3,200 mg/kg group. Animals were observed for 7 days including the day of treatment. There were no mortalities in the 200, 400, 800, and 1,600 mg/kg dose groups. Five of six mortalities occurred in the 3,200 mg/kg dose group within 4 days of treatment, and 6/6 mortalities in the 6,300 mg/kg dose group on day–1 of treatment. All animals which survived gained weight during the observation period. There were no treatment-related changes on gross necropsy. The oral lethal dose $(LD)_{50}$ (95% confidence interval) was 2,664 mg/kg for males and females combined.

ii. *Acute dermal*. Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was administered to four rabbits per dose level. Each dose group was topically treated for 24 hours with 160, 320, 630, 1,300, 2,500, or 5,000 mg/kg of undiluted test material (moistened with 5 meters/Liter (m/L) of distilled water) and with 250, 500, 1,000, and 2,000 mg/kg of the material as a 50% aqueous solution. In the undiluted test group, mortality rates were as follows: 160 mg/kg (0/4); 320 mg/kg (1/4); 630 mg/kg (1/4); 1,300 mg/kg (4/4); 2,500 mg/kg (2/4); 5,000 mg/kg (3/4).

The acute dermal LD_{50} (95% confidence interval) was 923 mg/kg for males and females combined with undiluted test material. Lethargy and anorexia were reported in the surviving animals. Topical reactions ranging from slight erythema to marked swelling and necrosis were observed. Treatment-related necropsy lesions (decreased abdominal adipose tissue, serous atrophy of the remaining adipose tissue and thymic atrophy) were observed at the two highest dose levels. The lesions were judged to be the result of stress and decreased appetite.

The number of mortalities observed in the 50% aqueous preparation was as follows: 250 mg/kg (1/4); 500 (3/4); 1,000 (1/4); 2,000 (4/4).

The acute dermal LD_{50} (95% confidence interval) was 605 mg/kg for males and females combined. Lethargy and anorexia were observed in the three lowest dose groups; lethergy and rapid, shallow breathing were seen in the highest dose group. Topical reactions ranging from slight edema to marked necrosis were reported. There were no lesions on necropsy attributable to treatment.

iii. *Acute inhalation*. In an acute inhalation study 10 rats (5 males/5 females) were exposed to 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane cloride and cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. There were no mortalities during the exposure period nor during the post-exposure observation period. There was generalized soiling and test material stains on fur. All animals exhibited a significant weight loss (9–11%) in the first few days post-exposure. Weight gain resumed 4 days post-exposure to end of study. Normal activity throughout the test period continued to the end of the study. One animal had unilateral corneal opacity. All other tissues and organs examined were normal. The acute inhalation toxicity lethal dose $(LC)_{50}$ to 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride and cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was greater than 4.7 milligrams/Liter (mg/L).

iv. *Primary eye irritation*. In a primary eye irritation study, nine New Zealand white rabbits had a 1 gram dose of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride instilled into the conjunctival sac of the right eye of each of six rabbits (Groups A). The same procedure was followed with three other rabbits (Group B), however these eyes were washed with tap water after a 30–second exposure period. The left eye served as an untreated control in all of the animals. Twenty four hours prior to treatment, the eyes of all nine rabbits were examined using 5% fluoresein stain and found to be normal. The eyes were examined 1, 2, 3, 4, and 7 days after the instillation and scored for evidence of damage to the conjunctival (redness, chemosis, and discharge), cornea (degree of opacity and area of cornea involved), and iris (area involved). In Group A rabbits, there was slight (3/6) or moderate (1/6) conjunctival redness and slight (1/6) conjunctival discharge. In Group B rabbits, there was slight (2/3) conjunctival redness. No corneal opacity was observed with either group. Signs of irritation were absent 72 and 48 hours in Groups A and B, respectively. The test material was determined to be a slight primary eye irritant.

v. *Primary dermal irritation*. In a primary dermal irritation study, 0.5 grams of undiluted cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was applied to the backs of six rabbits to an intact and an abraded site on each animal. The areas were covered with gauze patch and then a piece of heavy-gauge Saran® film. Elizabethan collars were placed on the rabbits to prevent ingestion. After 24 hours of exposure, the bandages were removed and each site was scored on a scale of 0 (normal) to 4 (severe) for dermal irritation (erythema and edema) then, and again at 72 hours from the

initial exposure. There was no evidence of erythema in the intact skin at either time point. The abraded skin on one animal showed a slight erythematous reaction at 24 hours; at 72 hours, two abraded areas were graded very slight and one moderate. The intact skin of one animal showed very slight edematous reaction at 24 hours. The abraded areas had either a very slight or slight edematous reaction at both time points. Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was considered to be only a slight irritant.

vi. *Dermal sensitization*. The dermal sensitization potential of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was tested using the modified Maguire method. Ten male Hartley Albino guinea pigs received four induction doses of 0.1 milliliter (mL) of 10% solution of the cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride in 8 days. Freund's Adjuvant was injected intradermally adjacent to the site at the time of the third application. On challenge 2 weeks after the last induction application, the test material produced a positive response in one animal. The positive control, a 10% solution of DER 331 epoxy resin, confirmed that the test system was operating appropriately. The study demonstrated that a 0.1 mL dose of a 10% solution of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is not a dermal sensitizer in guinea pigs.

2. *Genotoxicity*. Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was mutagenic in the *in vitro* Chinese hamster ovary (CHO) cell hypoxanthine guanine phophoribosyl transferase (HGPRT) forward mutation assay with activation but nonmutagenic without activation. Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was negative in the rat hepatocyte unscheduled deoxyribonucleic acid (DNA) synthesis assay. It was negative also in the mouse micronucleus test.

3. *Reproductive and developmental toxicity*. A dermal developmental toxicity study was conducted with Fischer 344 rats. Doses of 0, 250, or 500 mg/kg/day of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride as a 50% aqueous solution were applied to the dorsal skin daily on gestation days 6 through 15. No significant adverse effects from treatment with the test compound were found but the study was considered adequate because the doses were sufficiently high.

4. *Subchronic toxicity*—i. *Dermal subchronic study*. In a 13–week dermal subchronic study, New Zealand white rabbits were given dermal applications of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride for 13 weeks. The doses were 0, 50, 200, or 1,000 mg/kg/day. The only treatment related effect was a dose-dependent increase in ulcerative dermatitis, at the treatment site, that was correlated with the abrasions from clipping. The NOAEL for systemic toxicity was 1,000 mg/kg/day.

ii. *A 90–day oral subchronic study*. One study was conducted to determine the level of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride in the diet which would result in complete acceptance of the diet by rats. Ten rats/sex/group were administered the chemical in the diet at dosages of 0, 1, 2, or 4 mg/kg/day for 90 days. The only parameters evaluated were body weight, food consumption, and organ weight (absolute and relative). Male rats in the 4 mg/kg/day group had a significant decrease in body weight at approximately 36% of the weighing periods. This group also had a significant decrease in food consumption throughout the study. The absolute weight of the heart in the 4 mg/kg/day group males was significantly decreased. The relative weight of the brain and liver were increased in the 4 mg/kg/day group of females.

iii. *A 90–day oral subchronic study*. In another study, cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was administered in the diet to groups of 10 rats/sex/group at dosages of 0, 7.5, 15, 30, and 60 mg/kg/day for 90 days. Mean body weight was significantly decreased in all the treated males and females throughout the study. Overall mean body weight gain was decreased in all the treated groups. Mean food consumption was significantly decreased in the treated males, especially at the beginning of the study. Although all of the treated female groups had significantly reduced intake at some time during the study, females were not as frequently affected as males. Calculation of feed efficiency values for the overall study and for the latter half of the study showed that the major effect of decreased food intake on body weight occurred at the beginning of the study. However, the decrease in food efficiency does indicate that the chemical had a toxic effect on body weight that cannot be accounted for solely by decreased food consumption. The only other possible effect of treatment was an increase in the incidence of minimal hepatocellular swelling in the 60 mg/kg/day group males (0/5 in the control vs. 3/5 in the 60 mg/kg/day group).

iv. *A 90–day oral subchronic study*. In a dog study, cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride was administered in gelatin capsules to four Beagle dogs/sex/group at dosages of 0, 7.5, 15, or 30 mg/kg/day for 90 days. One female in the 30 mg/kg/day was sacrificed due to general deterioration on the 84th day of the study; necropsy revealed ascites with evidence of liver toxicity. The only other toxicologically significant findings during the study included a significant decrease in the hematocrit (HCT), hemoglobin (Hgb), and white blood count (WBC) measurements in the 30 mg/kg/day group males and histopathological changes, especially in the liver, in the 30 mg/kg/day group males and females. The incidence and/or severity of several findings in the liver were increased in the 30 mg/kg/day group males and females during the following:

- Obliterative vasculitis and perivasculitis of the hepatic blood vessels.
- Perivascular and pericholangiolar infiltration of mononuclear cells.
- Hyperplasia of the reticuloendothelial cells lining the hepatic sinusoid.

5. *Endocrine disruption*. No specific tests have been conducted with cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there are no significant findings in other relevant toxicity tests, *i.e.*, developmental toxicity, which would suggest cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride produces effects characteristic of the disruption of endocrine function.

C. Aggregate Exposure

Dietary exposure. The proposed use of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride as a preservative in end-use product formulations applied to growing crops is not expected to result in significant additional dietary exposure, due to the low concentration of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride employed in the formulation and the extremely low probability of contact by the general public following treatment.

Cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride,

when used according to good manufacturing practices, meets the requirements of food additive regulations in 21 CFR 175.105 for use as a preservative in adhesives; 21 CFR 176.1680 for preservation of polyurethane resins in contact with dry bulk foods; 21 CFR 176.170 for preservation of components of paper and paperboard intended for use in contact with aqueous and fatty foods; and 21 CFR 176.180 for preservation of components of paper and paperboard intended for use in contact with dry foods. These uses are not expected to result in quantifiable residues in the diet when used as a preservative, at low levels, in end-use agriculture pesticide formulations applied to growing crops.

D. Cumulative Effects

There is no reliable information that would indicate or suggest that cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride has any toxic effects on mammals that would be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population.* The Dow Chemical Company believes that based on the following information it is not expected that a tolerance for cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is required because:

- The cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is practically nontoxic to slightly toxic to humans.
- It will not pose a significant risk to humans.
- The parent compound as well as formaldehyde formation dissipate fairly rapidly under hydrolysis.
- The level of cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride to be included as a preservative in pesticide formulations applied to growing crops will be at low levels (0.14% by weight or less).

Therefore, it is not anticipated that a tolerance for the cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride would be necessary to protect the public health.

2. *Infants and children.* An exemption from a tolerance as proposed is expected to be negligible and not place infants and children at increased health risks.

F. International Tolerances

There are no known international tolerances for cis-isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride.

[FR Doc. E3–00560 Filed 12–16–03; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7596–1]

Notice of Proposed Settlement Under Section 122(h)(1) of the Comprehensive Environmental Response, Compensation and Liability Act; In the Matter of American Woodcraft Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Notice, request for public comment.

SUMMARY: Notice of Settlement: in accordance with section 122(i)(1) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (''CERCLA''), notice is hereby given of a settlement concerning past response costs at the American Woodcraft Superfund Site, in Union City, Michigan. This settlement requires Comerica Bank to pay $13,837.64 to the Hazardous Substances Superfund.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the Superfund Records Center, located at 77 West Jackson Boulevard, Seventh Floor, Chicago, Illinois.

DATES: Comments must be provided on or before January 16, 2004.

ADDRESSES: The proposed settlement and additional background information relating to the settlement are available for public inspection at the Superfund Records Center, located at 77 West Jackson Boulevard, Seventh Floor, Chicago, Illinois 60604. A copy of the proposed settlement may be obtained from the Superfund Records Center. Comments should reference the American Woodcraft Superfund Site and EPA Docket No. V–W–04–C–765 and should be addressed to Karen L. Peaceman, Associate Regional Counsel, 77 West Jackson Boulevard (C–14J), Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Karen L. Peaceman, 312–353–5751. Mail Code C–14J, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Authority: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9601 *et seq.*

Thomas W. Mateer,

Acting Director, Superfund Division.

[FR Doc. 03–31119 Filed 12–16–03; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7596–2]

Notice of Proposed Administrative Settlement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, as Amended by the Superfund Amendments and Reauthorization Act; Polar Star Superfund Removal Site

AGENCY: Environmental Protection Agency.

ACTION: Notice, request for public comments.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed CERCLE 122(H) Agreement for Recovery of Past Response Costs (''Agreement'') concerning the Polar Star Superfund Removal Site in Dutch Flat, California with Desert Star Group, Inc. (''DSGI'') and Tuli P. Haromy, the sole shareholder and sole officer of DSGI. The Agreement requires the settling parties to sell all the real property parcels owned by DSGI in Dutch Flat, and to pay 95% of the net proceeds from such sales to the U.S. Environmental Protection Agency (the ''Agency'' or ''USEPA'') Hazardous Substance Superfund. All property must be listed with a real estate listing agent for a period of one year from the effective date of the Agreement. If any property is not sold within that period, it must be offered for sale at a public auction. Upon performance of the Agreement by the settling parties, the settling parties shall have resolved any and all civil liability to USEPA under section 107(a) of CERCLA, 42 U.S.C. 9607 (a), for reimbursement of past response costs. For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the Agreement. The Agency will