

appear to be secondary to general systemic toxicity that occurs at high dose levels. Based on available data and structure-activity relationship analyses, mepiquat chloride would be considered to have minimal neurotoxic activity.

E. Safety Determination

1. *U.S. population.* In the mepiquat chloride RED, EPA has determined that the established tolerances for mepiquat chloride meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from the feed use on cotton, as well as the possibility of cumulative effects from mepiquat chloride and other chemicals with a similar mode/mechanism of toxicity. BASF does not believe that the use of mepiquat pentaborate on cotton alters these conclusions.

Since there are no residential or lawn uses of mepiquat, no dermal or inhalation exposure is expected in and around the home. No acute toxicity endpoints of concern have been identified for mepiquat.

In assessing chronic dietary risk, EPA estimates that mepiquat residues in food account for <1% of the RfD and residues in drinking water are not expected. Thus, the aggregate exposures from all sources of mepiquat (in this case, only dietary is relevant) account for <1% of the RfD for the general population. Therefore, the Agency concludes that aggregate risks for the general population resulting from mepiquat uses are not of concern.

In evaluating the potential for cumulative effects, EPA compared structural similarities and toxic effects seen in mepiquat chloride studies with other related compounds. With one substance, difenzoquat, there appears to be similar neurotoxic effects. However, the Agency has concluded that the cumulative effects from the combined dietary exposure to mepiquat chloride and difenzoquat would be virtually nil because the chronic dietary exposure for all population subgroups is less than 1% of the RfD for both difenzoquat and mepiquat chloride.

2. *Infants and children.* In the RED, EPA has determined that the established tolerances for mepiquat chloride (including the previously established temporary tolerances for grapes) meet the safety standard under the FQPA amendment to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the

general population, but also, takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of mepiquat chloride residues in this population subgroup.

In the developmental studies, effects were seen in the fetuses only at the same or higher dose levels than effects on the mothers. In the reproduction study, no effects on reproductive performance were seen. Also, because the NOAELs from the developmental and reproduction studies were equal to or greater than the NOAEL used for establishing the RfD, EPA concludes that it is unlikely that there is additional risk concern for immature or developing organisms. Finally, the Agency has no epidemiological information suggesting special sensitivity of infants and children to mepiquat chloride. Therefore, EPA finds that the uncertainty factor (100X) routinely used in RfD calculations is adequately protective of infants and children, and an additional uncertainty factor is not warranted for mepiquat.

EPA estimates that mepiquat residues in the diet of infants and children account for less than 1% of the RfD and residues in drinking water are not expected. Thus, the chronic aggregate exposure from all sources of mepiquat account for less than 1% for infants and children. The acute dietary MOE for infants and children exposed to mepiquat is 3,893. Therefore, the Agency concludes that aggregate risks for infants and children resulting from mepiquat uses are not of concern.

F. International Tolerances

There are no Codex, Canadian, or Mexican tolerances established for mepiquat on cotton. Thus, international harmonization is not an issue for these tolerances.

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ENVIRONMENTAL PROTECTION AGENCY

[PF-1051; FRL-6808-6]

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-1051, must be received on or before December 17, 2001.

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-1051 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8373; e-mail address: alston.treva@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" "Regulation 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-1051. 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-1051 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-1051. 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: November 2, 2001.

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. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous information, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position 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.

C. P. Hall Company

PP 1E6257

EPA has received a pesticide petition (1E6257) from The C.P. Hall Company, 311 S. Wacker, Suite 4700, Chicago, IL

60606 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for N,N-dimethyloctanamide, CAS Reg. No. 1118-92-9 and N,N-dimethyldecanamide, CAS Reg. No. 14433-76-2, when used as an inert ingredient as an emulsifier, solvent and cosolvent in pesticide formulations applied only to growing crops at less than 15% of the total formulation by weight. 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

Analytical method. Since this petition is for an exemption from the requirement of a tolerance, an analytical method is not required.

B. Toxicological Profile

i. *Acute toxicity—i. Daphnia magna.* The acute toxicity of *daphnia magna* was conducted for 48 hours with results as follows: 24-hour LC₅₀ (lethal concentration) estimated to be >4.0 milligram/liter (mg/L) (95% C.I. (confidence interval) could not be determined). 48-hour LC₅₀ = 7.7 mg/L (95% C.I. = 6.2 and 10 mg/L). 24-hour NOEC (no observed effect concentration) = 4.0 mg/L, 48-hour NOEC = 4.0 mg/L, 48-hour Dose Response Slope was 6.0.

ii. *Rainbow trout.* The acute toxicity to rainbow trout was determined in a static 96-hour test according to OECD (Organization for Economic Cooperation and Development) guideline 203. In this test, 5 groups of 10 fish were exposed to nominal concentrations of 5.00, 8.89, 15.8, 28.1 and 50.0 mg/L. During test duration the test concentration in the mean were higher than 80% of nominal values. The test revealed the following results: LC₅₀ = 21.1 mg test substance/l, LLC (lowest lethal concentration) = 28.1 test substance/l, LT (lethal threshold) = 21.2 mg/L, NOEC (no observed lethal effect concentration) = 15.8 mg/L, LOEC (lowest observed effect concentration) = 8.89 mg/L, effect threshold (geometric mean of LOEC and NOEC) = 6.67 mg and NOEC = 5.00 mg/L.

iii. *Bobwhite quail.* The acute oral toxicity to the Bobwhite Quail was conducted. LD₅₀ (lethal dose) = 1,600

mg/kg (95% confidence level) = 1,600–3,200 milligram/kilogram (mg/kg), lowest lethal dose = 1,600 mg/kg, LT = 1,130 mg/kg, highest dose without lethal effects = 800 mg/kg, LOEC = 800 mg/kg, threshold for effects = 570 mg/kg, NOEC = 400 mg/kg.

iv. *Rat dermal.* An acute dermal toxicity study was conducted on the male rat with a result of approximately 2,000 mg/kg and the female rat with a result of 400–200 mg/kg using method OECD guideline 402. The test substance was of moderate toxicity to female rats and of low toxicity to male rats following acute dermal application.

v. *Rat inhalation.* An acute inhalation study was performed using OECD guideline 403 on the male and female rat with a result of > 3,551 mg/m³ air; aerosol, exposition of 4 hours. The results of this study show that the respirable test article aerosol had a relatively low acute inhalative toxic effect on the rat. The acute potential hazard of the respiratory tract is attributed to the potency of the test substance aerosol as a mucosa irritant.

vi. *Corrosivity.* The corrosivity potential of the compound was evaluated in general compliance with the conditions specified by the Department of Transportation Hazardous Materials Regulation. No evidence of corrosion (necrosis) was found. The test material is not classified as a corrosive by dermal application, as defined by the Department of Transportation Hazardous Material Regulation.

vii. *Guinea pig sensitization.* The potential of the test substance as a 5% w/v formulation in 80% ethanol/20% distilled water, to produce delayed contact hypersensitivity in guinea pigs was evaluated. Following primary challenge, there were no grades of one produced in the test or control animals. The incidence and severity of these responses in the test group were essentially comparable to those produced by the naive control group indicating that sensitization had not been induced.

viii. *Minnow.* The acute toxicity of the compound to the fathead minnow was assessed. The results of the 4-day static fish toxicity study: 96-hour LC₅₀ (95% C.I.) 19 mg/L, (10 to 32 mg/L). The slope of the 96-hour dose response line was 9.2. The 32 mg/L concentrations resulted in 100% mortality within 24 hours.

ix. *Eye irritation.* Acute eye irritation was evaluated. Although the eye study was not allowed to progress to a point where formal classification could be applied, the eye irritation which resulted from exposure to this test

material strongly suggests classification in Toxicity Category I.

x. *Rat-oral.* The acute oral LD₅₀ value was estimated to be 1.77 g/kg in male and female Sprague-Dawley rats, which is Toxicity Category III.

xi. *Skin irritation-rabbit.* Due to the suspected irritation potential of this test material, a single animal was initiated on this primary skin irritation study. Due to the effects exhibited in this single animal, this study was ultimately terminated without testing in additional animals. Critical changes noted in the coloration and/or texture of the skin included necrosis, slight fissures, coriaceousness (leather-like), and light and dark brown discoloration. Evidence of corrosion was also found.

2. *Genotoxicity.* The *Salmonella*/microsome test for point mutagenic effects in doses of up to 5,000 µg per plate. Evidence of mutagenic activity was not seen. No biologically relevant increase in the mutant count in comparison with the negative controls, was observed. The compound was evaluated for mutagenic effects at the HGPRT locus in V79 cell cultures. There was no significant dose-related or reproducible increase in mutant frequency above that of the negative controls. Based on results, the test substance, is considered to be nonmutagenic in the V79-HGPRT Forward Mutation Assay, both with and without metabolic activation. The clastogenic potential of the compound was evaluated in a chromosome aberration test *in vitro*. Based on this test, the compound is not considered to be clastogenic for mammalian cells with and without metabolic activation *in vitro*. The compound was evaluated for genotoxicity in the *In Vitro* Rat Primary Hepatocyte Unscheduled DNA Synthesis (UDS) Assay. Based on the results, the test article was evaluated as inactive in the *In Vitro* Rat Primary Hepatocyte UDS Assay.

3. *Reproductive and developmental toxicity—i.* In pregnant Chinchilla rabbits, at 100 mg/kg body weight/day, reduced food consumption and body weight gain were noted during the dosing period. No effects on the dams were ascertained at 100 or 300 mg/kg of body weight/day. The fetal parameters were not affected up to and including the highest dose level of 1,000 mg/kg body weight/day. The maternal NOAEL 300 mg/kg and the developmental NOAEL is 1,000 mg/kg body weight/day. The test substance did not reveal any teratogenic potential up to and including the highest dose level of 1,000 mg/kg body weight/day.

ii. An embryo toxicity study including teratogenicity was performed on the rat.

Based on the results, the maternal NOAEL is 50 mg/kg body weight/day and the developmental NOAEL is 150 mg/kg body weight/day. This study did not reveal any teratogenic potential up to and including the highest dose level of 450 mg/kg body weight /day.

4. *Subchronic toxicity*— i. *Rat inhalation*. An orientation study for subacute inhalation toxicity was conducted with an aerosol of the test substance on the Wistar rat. 111.2 mg of the test substance air was tolerated without specific effects occurring with regard to all parameters determined.

ii. *Rat oral*. The test substance was administered in feed to 10 male and 10 female Wistar rats for 13 weeks at 0, 400, 2,000, and 10,000 ppm. Clinical chemistry, gross pathological and histological examination revealed no evidence of test article-related liver lesions up to and including 2,000 ppm. Increased plasma cholesterol values following 10,000 ppm indicate slightly impaired fat metabolism in the liver. This finding was not correlated histopathologically. There were no unusual findings among the clinical parameters measured at the end of the recovery period.

iii. *Dog*. In a subacute toxicity study group of two male and two female beagle dogs treated with the test substance, there was no difference exhibited between the control group and the treatment group either in the hematological parameters or in the clinical chemistry.

C. Other Information

1. The toxicity of green algae was conducted using OECD guideline method 201. The results show the *Selenastrum capricornutum* growth rate (72 h) EC₅₀ (effective concentration) =16.06 mg/L. The 95% confidence limits: 7.95-32.45 mg/L. The effect threshold was 2.40 mg/L. The toxicity of bacteria was conducted using OECD guideline 209 with results of: EC₅₀ = 212 mg/L.

2. A Tier I seed germination, seedling emergence, and vegetative vigor phytotoxicity study was conducted.

The results from the analysis of the substance Tier I germination test for lettuce and radishes indicated that a significant difference did exist. No germination was present for the lettuce in treatment (100 ppm). Radish had a low germination of 26% for 100 ppm treatment, a detrimental effect greater than 25% compared to the control. The emergence test indicated a significant difference for lettuce in the substance at 113 ppm treatment, showing a detrimental effect greater than 25% compared to the control. Radish in the

emergence test indicated no significant difference between treatments. The vegetative vigor test indicated the dicot species lettuce and radish had no significant effects from the exposure to the test compound 113 ppm treatment level.

D. Aggregate Exposure

1. *Dietary exposure*. For the purpose of assessing the potential dietary exposure, the C.P. Hall Company considers that the compound could be present in all raw and processed agricultural commodities.

i. *Food*. Both constituents are neither permitted nor prohibited in food, animal feeding stuffs, medicines or cosmetics under European directives. The material is listed in the "comprehensive list" of pesticide product inert ingredients and categories in "List 3" (inerts of unknown toxicity). No concerns for risk associated with any potential exposure scenarios are reasonably foreseeable given the available data.

ii. *Drinking water*. The lack of observed toxicity would indicate that the presence of trace amounts of the compound in drinking water would pose no appreciable risk to humans. The test substance is relatively insoluble in water (0.17% in water at 25 °C) and is not expected to create any drinking water toxicity. The rate of hydrolysis and its degradation pattern in aqueous buffer solutions showed that the compound was hydrolyzed to negligible extent at pH 5, 7, and 9 at 25 °C within 30 days. The adsorption and desorption of the compound was determined in four soils. Based on the study the compound is of low or medium to low mobility in the soils used in this study. The direct photolysis of the compound showed that it was stable against direct photolysis at pH 5.0 during illumination at 25 °C for 30 days. The half-life was much greater than 30 days. A study was conducted to determine the rate of photolysis and degradation. During illumination on soil thin layer plates the material was degraded and mineralized. No specific photodegradation product with more than 4.2% of the applied radioactivity was found.

E. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that when considering whether to establish, modify, or revoke a tolerance, or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of the chemicals residues. This compound has been used in European pesticides for a number of decades

without any signs of acute or chronic exposure toxicity.

F. Safety Determination

1. *U.S. population*. Since the material may be used in a European formulation of a pesticide and no toxicological effects have been shown, no risks are anticipated for the U.S. population.

2. *Infants and children*. Due to the extensive available toxicological data base and the expected low toxicity of this compound, C.P. Hall Company does not believe a safety factor analysis is necessary in assessing the risk of this compound.

G. International Tolerances

To C. P. Hall's knowledge no international tolerances exist for this compound.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7102-2]

Recent Posting of Agency Regulatory Interpretations Pertaining to Applicability and Monitoring for Standards of Performance for New Stationary Sources and National Emission Standards for Hazardous Air Pollutants to the Applicability Determination Index (ADI) Database System

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: In accordance with the Administrative Procedure Act (5 U.S.C. 552(a)), and the Clean Air Act provisions for judicial review (42 U.S.C. 7607(b)), this notice announces interpretations of applicability and alternative monitoring decisions that have been made by the EPA under the New Source Performance Standards (NSPS), and the National Emission Standards for Hazardous Air Pollutants (NESHAP).

DATES: Comments on any of the documents posted on the ADI database system must be submitted on or before January 14, 2002.

ADDRESSES: Comments may be submitted to the attention of Maria Malave; Mail Code 2223A; Compliance Assessment and Media Programs Division, Office of Compliance, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460 or send via E-mail to malave.maria@epa.gov.