of toxicity with other substances, or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, Dow AgroSciences has not assumed that tebufenozide has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions previously described, and taking into account the completeness and reliability of the toxicity data, Dow AgroSciences has concluded that dietary (food only) exposure to tebufenozide will utilize 21% of the chronic population adjusted dose (cPAD) for the U.S. population. EPA generally has no concern for exposures below 100% of the cPAD. Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. The modeling data for tebufenozide indicate levels less than the Agency's DWLOCs. There are no chronic non-occupational/residential exposures expected for tebufenozide. Therefore, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to tebufenozide residues.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

Using the exposure assumptions previously described, and taking into account the completeness and reliability of the toxicity data, the dietary (food only) exposure to tebufenozide will utilize 51% of the cPAD for the most highly exposed population subgroup (children 1–6 years old). EPA generally has no concern for exposures below 100% of the cPAD. Despite the potential for exposure to tebufenozide in drinking water and from non-dietary non-occupational exposure, Dow AgroSciences does not expect the aggregate exposure to exceed 100% of the RfD.

F. International Tolerances

Codex maximum residue levels have been established for residues of tebufenozide in/on pome fruit (1.0 ppm), husked rice (0.1 ppm) and walnut (0.05 ppm). Tebufenozide is registered in Canada, and a tolerance for residues in/on apples is established at 1.0 ppm. EPA has set the pome fruit tolerance at 1.5 ppm based on U.S. field residue trials.

[FR Doc. 03–5912 Filed 3–11–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0022; FRL–7295–9]

Dimethenamid; 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 ID number OPP–2003–0022, must be received on or before April 11, 2003.

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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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:

- Industry (NAICS 111), *e.g.*, Crop production.
- Industry (NAICS 112), *e.g.*, Animal production.
- Industry (NAICS 311), *e.g.*, Food manufacturing.
- Industry (NAICS 32532), *e.g.*, 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 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit I.A. 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 identification (ID) number OPP–2003–0022. 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 the EPA 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. 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–2003–0022. 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–2003–0022. 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–2003–0022.

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–2003–0022. 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: March 4, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner 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.

PP 0E6196

EPA has received a pesticide petition (PP 0E6196) from the Interregional Research Project No. 4 (IR–4), Technology Centre of New Jersey, Rutgers, the State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.464 by establishing tolerances for residues of dimethenamid, (R,S)-2-chloro-*N*-[(1-methyl-2-methoxy) ethyl]-*N*-(2,4-dimethyl-thien-3-yl)-acetamide in or on the raw agricultural commodities beet, garden, roots at 0.01 parts per million (ppm); beet, garden, tops at 0.01 ppm; beet, sugar, roots at 0.01 ppm; beet, sugar, tops at 0.01 ppm; garlic, dry bulb at 0.01 ppm; horseradish at 0.01 ppm; onion, dry bulb at 0.01 ppm, shallot, dry bulb at 0.01 ppm; and tuberous and corm vegetables subgroup (Crop group 1C) at 0.01 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition. This petition summary was prepared by the registrant, BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709–3528.

A. Residue Chemistry

1. *Plant and animal metabolism.* BASF Corporation notes that metabolism in plants and animals is understood.

2. *Analytical method.* The proposed analytical method uses extraction and clean-up followed by quantification with capillary column gas chromatography (GC) using thermionic nitrogen specific detector. A GC/mass spectrocopy (MS) method for identification is also available. This method is not selective towards the dimethenamid isomer and is therefore valid for residues from both dimethenamid and the enriched dimethenamid-P. Tolerances are proposed based on a non-isomer specific basis.

3. *Magnitude of residues.* For onion, magnitude of the residue data are based on applications with dimethenamid. Residue trials were conducted at 8 locations in California, Michigan, New York, Oregon, Texas, Washington, and Wisconsin. Treatments were made at 1.5 lbs active ingredient/acre (ai/A) 30 or 45 days before harvest. No residues above the limit of quantitation (LOQ) of 0.01 ppm were detected in dry bulb onion. Residue data from dry bulb onion will be used as surrogate data for dry bulb garlic and shallots.

For sugar beet, magnitude of the residue data are based on dimethenamid-P applications to sugar beet at 0.98 lb ai/A. Dimethenamid-P is the biologically active isomer from the racemic dimethenamid mixture. The method measures both dimethenamid and dimethenamid-P, so the sugar beet residue determinations for dimethenamid-P are considered representative of the proposed treatments with dimethenamid. No residues were detected in sugar beet roots or tops from a testing program conducted in 12 locations across 8 states. Data from processing studies indicate that no residues are detected in the roots even at exaggerated rates of 3.15 lbs ai/A. The limit of quantitation is 0.01 ppm. The sugar beet trials also support the tolerances for table beet.

For the tuberous and corm vegetable subgroup, magnitude of the residue data for potatoes are based on applications with dimethenamid-P. Residue trials were conducted at 17 locations in California, Colorado, Florida, Idaho, Michigan, New Jersey, North Carolina, Oregon, Pennsylvania, Washington, and Wisconsin. Treatments were made at 1.25 lbs ai/A 40 days before harvest. No residues above the LOQ of 0.01 ppm were detected in potato tubers. Data from processing studies indicate that no residues are detected in the tubers even at exaggerated rates of 12.5 lbs ai/A. Residue data from potato tubers will be used as surrogate data for horseradish.

BASF believes that due to the low levels of residue in the RAC's, tolerances in animals are not required.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data, dimethenamid and dimethenamid-P do not pose an acute dietary risk. The acute toxicity studies place both technical materials in acute toxicity category II for acute oral; in acute toxicity category III for acute dermal, inhalation, and eye; and in acute toxicity category IV for dermal irritation. The technical materials are a positive skin sensitizer.

2. *Genotoxicity*. The following testing was performed with dimethenamid for genotoxicity. A modified ames test: Negative; *in vitro* CHO/HGPRT mammalian cell mutation assay: Negative; *in vitro* cytogentics - CHO cells (1 study; chromosome aberrations): Weakly positive; *in vitro* UDS test using rat hepatocytes (3 studies; DNA damage and repair): 2 negative; 1 equivocally positive, mouse micronucleus assay (2 studies; chromosome aberrations): Negative, rat dominant lethal assay: 1 study equivocally positive, 1 study negative. Overall dimethenamid has been tested in 14 genetic toxicology assays. The weight of the evidence demonstrates that dimethenamid is not genotoxic.

The following testing was performed with dimethenamid-P for genotoxicity. A modified ames test (3 studies; point mutation): Negative; *in vitro* CHO/HGPRT mammalian cell mutation assay (1 study; point mutation): Negative; *in vitro* cytogentics - CHO cells (1 study; chromosome aberrations): Negative; *in vitro* UDS test using rat hepatocytes (1 study; DNA damage and repair): Negative; mouse micronucleus assay (1 study; chromosome aberrations): Negative. Dimethenamid-P has been tested in a total of 7 genetic toxicology assays. These assays were performed both *in vitro* and *in vivo* and multiple assays were conducted for each of the three EPA Guideline requirement categories. Based on the data presented above, the data indicates that dimethenamid-P does not induce gene mutations, is not clastogenic and does not induce other effects indicative of genotoxicity. Therefore, BASF concludes that dimethenamid-P does not pose a mutagenic hazard to humans.

3. *Reproductive and developmental toxicity*—i. *Rat*. A developmental rat study using dimethenamid via oral gavage resulted in dosages of 0, 50, 215, and 425 milligram per kilogram (mg/kg)/day with a development toxicity no observed adverse effect level (NOAEL) of 215 mg/kg/day and a maternal toxicity of 50 mg/kg/day based on the following: (1) Signs of maternal toxicity, in the form of reduced body weight gain and food consumption, increased liver weight and clinical observations were observed at dose levels > 215 mg/kg/day with an increase in effects to the upper dose level; (2) at the = 215 mg/kg/day dose levels slight decreases in fetal body weights were observed which are not indicative a teratogenic effect; and (3) at the 425 mg/kg/day dose level a slight increase in resorptions was observed, and two fetuses had incomplete ossified manubria. These effects are not indicative of a teratogenic effect.

A developmental rat study using dimethenamid-P via oral gavage resulted in dosages of 0, 25, 150, and 300 mg/kg/day with a development toxicity NOAEL of 25 mg/kg/day and a maternal toxicity of 25 mg/kg/day based on based on the following: (1) Signs of maternal toxicity, in the form of decreased body weights and food consumption were observed at dose levels > 150 mg/kg/day with an increase in effects to the upper dose level; (2) at the 150 mg/kg/day dose level slight decreases in fetal body weights and retarded ossification of the pelvis pubis were observed which are not indicative a teratogenic effect; and (3) at the 300 mg/kg/day dose level slight decreases in fetal body weights, microphthalmia in two fetuses/two litters, distended ureters, and retarded ossification of the 2nd sternal centra and pelvis pubis were observed, similarly, these effects are not indicative of a teratogenic effect.

ii. *Rabbits*. A developmental study in rabbits using dimethenamid via oral gavage resulted in dosages of 0, 37.5, 75, and 150 mg/kg/day (HDT) with a development toxicity NOAEL of 75 mg/kg/day and a maternal toxicity of 37.5 mg/kg/day based on: (1) Decreased body weight, food consumption, and absorption/premature delivery in the 75 and 150 mg/kg/day dose groups; and (2) effects on fetal development were a low incidence of absorption/premature delivery and hyoid angulated changes in the 150 mg/kg/day dose group which are not are indicative of a teratogenic effect.

iii. *Two-generation reproduction - rats*. A two-generation reproduction study using dimethenamid with rats fed dosages of 0, 7.5, 38, and 155 mg/kg/day (average mg/kg/day dose levels for both male and female rats) with a reproductive NOAEL of 38 mg/kg/day and with a parental NOAEL of 38 mg/kg/day based on: (1) Parental toxicity as evident by reduction in body weight and food consumption and significant increases in absolute and/or relative liver weights in both males and female rats in the 155 mg/kg/day dose group; and (2) significant reductions in pup weight during lactation were observed in the 150 mg/kg/day dose group. No changes in pregnancy rates, fertility or length of gestation were observed at all dose levels tested.

4. *Chronic feeding and carcinogenicity*. The established reference dose (RfD) for dimethenamid and dimethenamid-P is based on a 2-year feeding study in rats with dimethenamid, with a threshold NOAEL of 5.1 mg/kg/day. Using an uncertainty factor of 100, the RfD is calculated to be 0.05 mg/kg/day. The following are summaries of the pertinent toxicity data supporting dimethenamid tolerances:

i. *Chronic feeding - nonrodent*. A 1-year feeding study in dogs fed dimethenamid at dosages of 0, 2, 9.6, or 49 mg/kg/day with a NOAEL of 9.6 mg/kg/day based on the following effects: (1) Slight decreases in body weights for both the high dose male and female dogs as compared to controls; (2) a variable degree of periportal hepatocyte vacuolation in the high-dose male and female dogs; (3) minimal or mild hepatocyte enlargement was similarly observed in the high-dose dogs; and (4) the liver changes at the high-dose group correlated with increase in serum alkaline phosphatase activity and cholesterol levels and increased liver-to-body weight ratios in both male and female dogs.

ii. *Chronic feeding/carcinogenicity - rat*. A combined chronic feeding/carcinogenicity study using dimethenamid was performed in rats being fed dosages of 0, 5.1, 36, and 80 mg/kg/day (males) and 0, 6.8, 49, and 109 mg/kg/day (females) with a NOAEL of 5.1 mg/kg/day (males) and 6.8 mg/kg/day (females) based on the following effects: (1) Decreased body weights in both males and female rat at dose levels > 36 mg/kg/day dose groups with a slight progression of severity to the upper level; (2) decreased food consumption in both males and female rats at dose levels > 36 mg/kg/day dose groups with a slight progression of severity to the upper dose level; (3) minimal hematological and clinical chemistry value changes at dose levels > 36 mg/kg/day dose groups with very slight increase of severity at the higher dose tested; (4) increased absolute liver weights for females at dose levels > 49 mg/kg/day; (5) microscopic findings were observed in the liver, parathyroid, and stomach of high-dose males, only, and ovaries of high-dose females; and (6) an increased incidence of benign and malignant tumors of the liver at the highest dose level tested. The liver tumors observed in this study occurred at an incidence which was slightly beyond the historical control range for this tumor type, and occurred at the

maximum tolerated dose (MTD). Given the lack of structural activity relationship (SAR) and the lack of mutagenicity discussed in section B.2., it is BASFs opinion that dimethenamid-P should not be considered a biologically relevant carcinogen in rats and the assessment is made that the results of this carcinogenicity study do not indicate a carcinogenic potential of the test substance for humans.

iii. *Carcinogenicity - mice*. A carcinogenicity study using dimethenamid in mice fed dosages of 0, 3.8, 41, 205, and 431 (HDT) mg/kg/day (males) and 0, 4.1, 41, 200, and 411 (HDT) mg/kg/day (females) with a NOAEL of 41 mg/kg/day for male and female mice based on the following effects: (1) Decreased body weights and food consumption were observed in both males and female mice at the highest dose tested; (2) increased liver weights were observed for male and female mice at the highest dose tested at an interim sacrifice and increased weights for kidney and liver were observed for female mice at dose levels > 200 mg/kg/day at terminal sacrifice; (3) microscopic findings were observed in the liver and stomach for both male and female mice at the upper dose levels; (4) concerning the finding in the stomach, EPA has determined that this finding was attributed to irritation of the material and the finding was not toxicology significant; and (4) no increased incidence of neoplasms occurred at any dose levels tested in this study. EPA has concluded that this product is not carcinogenic under the conditions of this study.

Dimethenamid is considered not to be carcinogenic in mice by BASF. In the rat carcinogenicity study, a slight increase in liver tumors was observed in males, only, at the highest dose tested. The liver tumors observed in this study occurred at an incidence that was slightly beyond the historical control range for this tumor type, and occurred at the MTD. Dimethenamid shares no common mechanisms with other compounds in the chloroacetanilide class of compounds. It is BASF's opinion that dimethenamid and dimethenamid-P should not to be considered biologically relevant carcinogens in rats and the assessment is made that the results of this carcinogenicity study do not indicate a carcinogenic potential of these substances for humans.

However, EPA has determined that dimethenamid is considered to be a Group C carcinogen - possible human carcinogen - based on the judgment of the EPA Carcinogenicity Peer Review Committee assessment. Also, the Committee determined for risk assessment purposes, the RfD approach should be used to quantify human risk. BASF agrees with the Agency that the RfD approach for human risk assessment is valid.

5. *Endocrine disruption*. No specific tests have been performed with dimethenamid-P or dimethenamid to determine whether the chemical may have an effect in humans that is similar to an effect produced by naturally occurring estrogen or other endocrine effects. However, there are no significant findings in other relevant toxicity studies, *i.e.* teratology and multi-generation reproductive studies, that would suggest the dimethenamid produces endocrine related effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* BASF has reviewed the available toxicology database to determine the endpoints of concern. For dimethenamid and dimethenamid-P, BASF believes there is no concern regarding an acute dietary risk since the available data do not indicate any evidence of significant toxicity from a 1 day or single event exposure by the oral route.

For the purpose of assessing the potential chronic dietary exposure, BASF has estimated aggregate exposure based on theoretical maximum residue contribution (TMRC) from the tolerance of dimethenamid on sweet corn, sorghum, peanuts, and dry beans at 0.01 ppm for all uses stated, respectively. The TMRC is a ''worse case'' estimate of dietary exposure since it is assumed that 100% of all crops for which the tolerances are established are treated and that pesticide residues are always found at tolerance levels. EPA in a letter issued on October 13, 1995, for dimethenamid, determined the TMRC for the crops mentioned in section C.1. to be 0.076 and 0.341 microgram (ug)/kg/day for the general U.S. population and non-nursing infants (< 1), respectively. Dimethenamid treated crops using the TMRC values utilized 0.15% and 0.683% for the general U.S. population and non-nursing infants (< 1), respectively, of the RfD (0.05 mg/kg/day). These assessments are also valid for dimethenamid-P. BASF concurs with this assessment.

The addition of an onion tolerance at 0.01 ppm has a TMRC of 0.0011 ug/kg/day for the general population and a TMRC of 0.0004 ug/kg/day for non-nursing infants. Sugar beet tolerances at 0.01 ppm, add 0.0033 ug/kg/day to the TMRC for the general population and 0.0013 ug/kg/day to the TMRC for non-nursing infants. The addition of table beet tops, dry bulb garlic, horseradish, and dry bulb shallot is negligible; table beet root tolerances at 0.01 ppm add 0.00022 ug/kg/day to the TMRC for the general population and 0.0019 ug/kg/day to the TMRC for non-nursing infants. The addition of potato tolerances at 0.01 ppm would contribute 0.011 ug/kg/day to the TMRC for the general population and 0.014 ug/kg/day to the TMRC for non-nursing infants. The addition of sweet potato tolerances at 0.01 ppm would contribute 0.00039 ug/kg/day to the TMRC for the general population and 0.0029 ug/kg/day to the TMRC for non-nursing infants. The total RfD utilization from all uses, both registered and proposed, is 0.18% for the general population, and 0.72% for non-nursing infants.

Therefore, based on the completeness and reliability of the toxicity data, and the exposure assessment discussed in section C.1., BASF concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of dimethenamid and dimethenamid-P, including all anticipated dietary exposure.

ii. *Drinking water*. Other potential sources of exposure to dimethenamid for the general population are residues in drinking water and exposure from non-occupational sources. In a dimethenamid-P environmental-fate risk assessment dated December 1998, EPA calculated the following maximum concentrations for drinking water: Based on SCI-GROW model calculations, ground-water concentrations were expected to be < 1.0 parts per billion (ppb). Based on PRZM/EXAMS model calculations for surface water, the maximum yearly average (chronic) concentration was 5.4 ug/l from a Southeast corn scenario. Using these values, the drinking water level of comparison (DWLOC) and the aggregate RfD utilization are summarized in the table below.

	U.S. population (% of RfD)	Non-nursing infants (% of RfD)
Chronic dietary exposure	0.18	0.72
Remainder RfD available for water (%) (drinking water level of comparison)	99.82	99.32

	U.S. population (% of RfD)	Non-nursing infants (% of RfD)
SCI-GROW ground water estimation[1]	< 0.10	0.20
PRZM/ EXAMS surface water estimation[1]	0.30	1.10
Total of RfD used by diet and water	0.58	2.00

[1]Used highest values predicted from the model for all agricultural uses. Assumes 2L/day and 70 kg adult; 1L/day and 10 kg infant.

2. *Non-dietary exposure*. For non-occupational exposure, dimethenamid/dimethenamid-P is not registered for either golf course or homeowner uses which could contribute to ''non-dietary or other exposure.''

D. Cumulative Effects

BASF has considered the potential for cumulative effects of dimethenamid and other substances that have a common mechanism of toxicity. BASF is aware of several other chloroacetanilide herbicides that have been considered structurally similar to dimethenamid, these being: Acetochlor, propachlor, butachlor, metolachlor, and alachlor. However, BASF believes that consideration of a common mechanism of toxicity to these products is not appropriate or valid. This conclusion was based on the presentation EPA made to the EPA FIFRA Science Advisory Panel (SAP) on March 20, 1997. The title of the presentation was ''Grouping of Chloroacetanilide Pesticides Based on a Common Mechanism of Toxicity.'' In this presentation EPA showed the structure of several chloroacetanilides that included dimethenamid. BASF is identifying Chlor–7 as dimethenamid. EPA concluded that Chlor–7 should not be considered to have a common mechanism to the other chloroacetanilides based on the following reasons:

- Except for Chlor–7 all other members of this case study have a potential to generate a quinone imine. The quinone imine intermediate, is capable of reacting with macromolecules.
- Chlor–7 has not produced nasal nor thyroid tumors in rats, thus does not support inclusion in the group for a common mechanism for these tumor types.

For liver tumors, Chlor–1, Chlor–7, Chlo–r5, and Chlor–6, can be potentially grouped for a common mechanism, but EPA determined that there is no knowledge of a common mechanism of toxicity or of a common toxic species responsible for the effect. Therefore, EPA concluded that because a mechanism can not be postulated, it believes that sufficient evidence is not available to support a common mechanism for this tumor type with these materials.

Therefore, BASF agrees with the position put forward by the Agency and confirmed by the SAP that a common mechanism is inappropriate for dimethenamid (Chlor–7) and the other chloroacetanilides mentioned in section D. BASF has considered only the potential risks of dimethenamid in its exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions described in section C., based on the completeness and the reliability of the toxicity data, BASF has estimated that aggregate exposure to dimethenamid will utilize < 1% of the RfD (0.05 mg/kg/day) for the U.S. population. EPA generally has no concern for exposure below 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data, and the exposure assessment discussed in sections B. and C., BASF concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of dimethenamid including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children*. BASF cites results of developmental toxicity studies reported in section B.3. including:

- Observed developmental toxicity effects in rats are not indicative of teratogenic effect.
- The results of developmental study in rabbits also demonstrated that dimethenamid is not a teratogenic compound and has a development toxicity NOAEL of 75 mg/kg/day and a maternal toxicity of 37.5 mg/kg/day.

BASF believes that these test results demonstrate that the rat and rabbit are similarly sensitive to dimethenamid. Additionally, the NOAEL of 5 mg/kg/day from the chronic rat study used to set the RfD is 7.5X and 5X lower than the maternal NOAELs established in the rabbit and rat teratology studies, respectively. The developmental effects observed in either the rat or rabbit occurred only at maternally toxic doses. Therefore, BASF concludes that no additional safety factor is needed for children.

F. International Tolerances

A maximum residue level has not been established under Codex Alimentarius Commission for dimethenamid for any of the proposed uses.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0043; FRL–7292–5]

Extension of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an extension of an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6502; e-mail address: sibold.ann@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, 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 identification (ID) number OPP–2003–0043. 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