ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0262; FRL–7321–7]

Dimethomorph; Notice of Filing Pesticide Petitions to Establish Tolerances for Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP–2003–0262, must be received on or before September 19, 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@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)
- Crop production (NAICS 112)
- Animal production (NAICS 311)
- Food 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–2003–0262. 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 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 on 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–2003–0262. 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–2003–0262. 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–2003–0262.

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–2003–0262. 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 pesticide petitions 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: August 11, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner's summary of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petitions were prepared by BASF Corporation and represents the view of BASF Corporation. 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.

Interregional Research Project Number 4 (IR-4)

PP 2E6483 and PP 3E6558

EPA has received pesticide petitions (2E6483 and 3E6558) from Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 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 180.493 by establishing tolerances for residues of dimethomorph, (E,Z)4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl morpholine in or on the following raw agricultural commodities: Vegetable, fruiting, group 8 at 2.0 parts per million (ppm) (2E6483), brassica, leafy, greens,

(subgroup 5B), and turnip, tops at 20 ppm (PP 3E6558), taro, leaves at 6.0 ppm (3E6558), and taro, roots at 0.5 ppm (3E6558). IR-4 also proposes to delete the existing tolerance for tomato, fruit at 0.5 ppm. Tomato is included in the proposed tolerance for the fruiting vegetable group 8 at 2.0 ppm. EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions. This summary has been prepared by BASF Corporation, Research Triangle Park, NC 27709.

A. Residue Chemistry

1. *Plant metabolism*. Based upon the results of metabolism studies conducted on potato, grape, and lettuce, the nature of the residues in plants is considered to be understood.

2. *Analytical method*. A reliable method for the determination of dimethomorph residues in fruiting vegetables (except cucurbits) (crop group 8), leafy brassica greens (subgroup 5B), turnip greens, taro leaves and roots exists; this method is the FDA Multi-Residue Method, Protocol D, as published in the Pesticide Analytical Manual I.

3. *Magnitude of residues*. The magnitude of residues for the proposed tolerances are adequately understood.

B. Toxicological Profile

1. *Acute toxicity*—i. Oral lethal dose LD_{50} studies were conducted on dimethomorph technical:

a. An acute oral toxicity study in the Sprague-Dawley rat for dimethomorph technical with a LD_{50} of 4,300 milligrams/kilogram body weight (mg/kg bwt) for males and 3,500 mg/kg bwt for females. Based upon EPA toxicity criteria, the acute oral toxicity category for dimethomorph technical is Category III or slightly toxic.

b. An acute toxicity study in the CD-1 mouse for dimethomorph technical with a LD_{50} of greater than 5,000 mg/kg bwt for males and 3,699 mg/kg/bwt for females. Based on the EPA toxicity category criteria, the acute oral toxicity category for dimethomorph technical is Category III or slightly toxic.

ii. Oral LD_{50} studies were conducted on the two isomers (E and Z) alone:

a. An acute oral toxicity study in the Wistar rat for the E-isomer with a LD_{50} greater than 5,000 mg/kg bwt for males and approximately 5,000 mg/kg bwt for females.

b. An acute oral toxicity study in the Wistar rat for the Z-isomer with a LD_{50} greater than 5,000 mg/kg bwt for both males and females.

iii. An acute dermal toxicity study in the Wistar rat for dimethomorph technical with a dermal LD_{50} greater than 5,000 mg/kg bwt for both males and females. Based on the EPA toxicity category criteria, the acute dermal toxicity category for dimethomorph is Category IV or relatively non-toxic.

iv. A 4–hour inhalation study in Wistar rats for dimethomorph technical with a lethal concentration LC_{50} greater than 4.2 milligram per liter (mg/L) for both males and females. Based on the EPA toxicity category criteria, the acute inhalation toxicity category for dimethomorph technical is Category IV or relatively non-toxic.

v. A skin irritation study was performed using New Zealand White rabbits. Based on EPA's toxicity criteria, the skin irritation toxicity category for dimethomorph technical in this study is Category IV or non-to-slightly irritating.

vi. An eye irritation study using New Zealand white rabbits demonstrated dimethomorph technical produced moderate conjunctival redness, slight to moderate chemosis and slight discharge 3 hours after treatment. Based on EPA's toxicity criteria, the eye toxicity category for dimethomorph technical is Category III (slightly to moderately irritating).

2. *Genotoxicity.*—i. *Salmonella* reverse gene mutation assays (2 studies) were negative up to a limit dose of 5,000 g/plate. Chinese hamster lung V79 cells were negative for mutations at the HGPRT locus at up to toxic doses in two studies.

ii. Two Chinese hamster lung (V79 cells) structural chromosomal studies were reportedly positive for chromosomal aberrations at the highest dose tested (HDT) (160 g/ml/-S9; 170 g/ml/+S9). However, dimethomorph induced only a weak response in increasing chromosome aberrations in this test system. In addition, these results were not confirmed in two micronucleus tests under *in vivo* conditions.

iii. Structural chromosomal aberration studies were weakly positive in human lymphocytic cultures, but only in S9 activated cultures treated at 422 g/mL, the HDT, which was strongly cytotoxic. No increase in chromosomal aberrations was observed in the absence of S9 activation at all doses. Furthermore, the positive clastogenic response observed under the *in vitro* conditions was not confirmed in two *in vivo* micronucleus assays.

iv. Micronucleus assay (2 studies) indicated that dimethomorph was negative for inducing micronuclei in bone marrow cells of mice following i.p. administration of doses up to 200 mg/kg or oral doses up to the limit dose of 5,000 mg/kg. Thus, dimethomorph was found to be negative in these studies for causing cytogenic damage *in vivo*.

v. Dimethomorph was negative for inducing unscheduled DNA synthesis, in cultured rat liver cells, at doses up to 250 grams per milliliter (g/ml), a weakly cytotoxic level.

vi. Dimethomorph was negative for transformation in Syrian hamster embryo cells treated, in the presence and absence of activation, up to cytotoxic concentrations (265 g/mL/+S9; 50 g/mL/-S9).

3. *Reproductive and developmental toxicity*—i. A rat developmental toxicity study with a lowest observed adverse effect level (LOAEL) for maternal toxicity of 160 mg/kg/day and a NOAEL for maternal toxicity of 60 mg/kg/day. The NOAEL for developmental toxicity is 60 mg/kg/day. Dimethomorph is not teratogenic in the Sprague-Dawley rat.

ii. A rabbit development toxicity study with a LOAEL for maternal toxicity of 650 mg/kg/day and a NOAEL for maternal toxicity of 300 mg/kg/day. The NOAEL for developmental toxicity is 650 mg/kg/day, the HDT. Dimethomorph is not teratogenic in the New Zealand white rabbit.

iii. A two-generation rat reproduction study with a LOAEL for parental systemic toxicity of 1,000 ppm, or approximately 80 mg/kg/day, and a NOAEL for parental systemic toxicity of 300 ppm, or approximately 24 mg/kg/day. The NOAEL for fertility and reproductive function was 1,000 ppm, the highest concentration tested (HCT), or approximately 80 mg/kg bwt/day.

4. *Subchronic toxicity*—i. A 90–day dietary study in Sprague-Dawley rats with a NOAEL of greater than or equal to 1,000 ppm, the HCT tested, or approximately 73 mg/kg/day for males and 82 mg/kg/day for females.

ii. A 90–day dog dietary study with a NOAEL of 450 ppm, or approximately 15 mg/kg/day, and a LOAEL of 1,350 ppm, or approximately 43 mg/kg/day.

5. *Chronic toxicity*–i. A 2–year chronic toxicity study in Sprague-Dawley rats with a NOAEL of 200 ppm or approximately 9 mg/kg/day for males and 12 mg/kg/day for females. The LOAEL for systemic toxicity is 750 ppm, or approximately 36 mg/kg/day for males and 58 mg/kg/day for females.

ii. A 1–year chronic toxicity study in dogs with a NOAEL of 450 ppm, or approximately 14.7 mg/kg/day and a

LOAEL of 1,350, or approximately 44.6 mg/kg/day.

iii. A 2–year oncogenicity study in Sprague-Dawley rats with a NOAEL for systemic toxicity of 200 ppm, or approximately 9 mg/kg/day for males and 11 mg/kg/day for females. The LOAEL for systemic toxicity was 750 ppm, or approximately 34 mg/kg/day for males and 46 mg/kg/day for females. There was no evidence of increased incidence of neoplastic lesions in treated animals. The NOAEL for oncogenicity is 2,000 ppm, the Highest Concentration Tested (HCT), or approximately 95 mg/kg/day for males and 132 mg/kg/day for females.

iv. A 2–year oncogenicity study in CD-1 mice with a NOAEL for systemic toxicity of 100 mg/kg/day and a LOAEL of 1,000 mg/kg/day. There was no evidence of increased incidence of neoplastic lesions in treated animals. The NOAEL for oncogenicity is 1,000 mg/kg/day, the HDT.

6. *Animal metabolism.* Results from the livestock and rat metabolism studies show that orally administered dimethomorph was rapidly excreted by the animals. The principal route of elimination is the feces.

7. *Metabolite toxicology.* There were no metabolites identified in plant or animal commodities which require regulation.

8. *Endocrine disruption.* Collective organ weights and histopathological findings from the two-generation reproduction study in rats, as well as from the subchronic and chronic toxicity studies in two or more animal species, demonstrate no apparent estrogenic effects or effects on the endocrine system. There is no information available which suggests that dimethomorph technical would be associated with endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure.* The CARES 1.1 model with the CSFII/FCID consumption data were used to calculate chronic and acute exposure estimates. Result exposure estimates 99.9th percentile were compared against the dimethomorph reference dose (RfD) and chronic population adjusted dose (cPAD).

i. *Food.* The dietary assessment analysis followed an initial tier approach with only one minor refinement. Tolerance values, default processing factors, and 100% crop treated (CT) values were assumed in the assessment. The only minor refinement was including percent crop treated values for potatoes (2.2%), tomatoes (0.1%), cucumbers (2.9%), and pumpkin (13.6%). Vegetables (fruiting, bulb, cucurbit), lettuce (leaf, head), grapes (including raisins), potatoes, hops, grain, brassica (leafy greens), leaves of root and tuber vegetables, and taro roots as the target crops were also considered for this analysis.

a. *Chronic.* Results of the chronic dietary exposure assessment for dimethomorph (BAS 550 F) are listed in Table 1. The estimated chronic dietary exposure for all current and pending commodities ranged from 7.5% to 15.2% of the %cPAD (0.1 mg/kg bwt/day) for all subpopulations.

TABLE 1.–CHRONIC DIETARY EXPOSURE ASSESSMENT FOR DIMETHOMORPH (BAS 550 F)

Population	Exposure Estimate (mg/kg bwt/day)	%cRfD	%cPAD
Birth to 1–year	0.007972	7.97	7.97
1–2 years	0.01513	15.13	15.13
3–5 years	0.01331	13.31	13.31
1–6 years	0.01512	15.12	15.12
6–12 years	0.007794	7.79	7.79
Teens 13–19 years	0.007482	7.48	7.48
Females 13–49 years	0.007771	7.77	7.77
Males 20–49 years	0.006853	6.85	6.85
Adults 50+ years	0.007548	7.55	7.55

b. *Acute.* Exposure estimates for the dimethomorph acute dietary assessment ranged from 0.064 to 0.174 mg/kg bwt/day for all subpopulations (Table 2). The %aRfd and %aPAD were not applicable for the acute dietary assessment since toxicology studies have shown that dimethomorph poses no acute dietary risk.

TABLE 2.—ACUTE DIETARY EXPOSURE ASSESSMENT FOR DIMETHOMORPH (BAS 550 F)

Population	Exposure Estimate (mg/kg bwt/day)	%aRfD	%aPAD
Birth to 1–year	0.1736	NA	NA
1–2 years	0.1742	NA	NA
3–5 years	0.1584	NA	NA
1–6 years	0.1654	NA	NA
6–12 years	0.09621	NA	NA

TABLE 2.—ACUTE DIETARY EXPOSURE ASSESSMENT FOR DIMETHOMORPH (BAS 550 F)—Continued

Population	Exposure Estimate (mg/kg bwt/day)	%aRfD	%aPAD
Teens 13–19 years	0.07855	NA	NA
Females 13–49 years	0.07306	NA	NA
Males 20–49 years	0.06386	NA	NA
Adults 50 + years	0.07058	NA	NA

Results of the chronic and acute dietary exposure analysis demonstrate a reasonable certainty that no harm to the general U.S. population or any subpopulation would results from the use of dimethomorph on vegetables (fruiting, bulb, cucurbit), lettuce (leaf, head), grapes (including raisins), potatoes, hops, grain, brassica (leafy greens), leaves of root and tuber vegetables, and taro root.

ii. *Drinking water.* EPA's Pesticide Root Zone Model/Exposed Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Groundwater (SCI-GROW) models were used to estimate the maximum dimethomorph concentrations in surface water and ground water, respectively. Results for the chronic drinking water assessment are listed in Table 3.

TABLE 3.—CHRONIC DRINKING WATER ASSESSMENT FOR DIMETHOMORPH

DWLOC chronic	Adult males 20–49	Adult females 13–49	Children 1–6 years	Children birth to 1
No effect level	9	9	9	9
Safety factor	100	100	100	100
RfD=	0.09	0.09	0.09	0.09
cPAD	0.09	0.09	0.09	0.09
A) Chronic food (mg/kg/day)	0.006853	0.007771	0.01512	0.007972
B) Residential (mg/kg/day)	0	0	0	0
water cPAD-(A+B)	0.08314700	0.10222900	0.07488000	0.08202800
DWLOC chronic µg/L	2910	3067	749	820
DEC's				
PRZM/EXAMS (EFED) surface water (µg/L)	12.65	12.65	12.65	12.65
Sci-Grow (EFED) ground water	0.26	0.26	0.26	0.26

2. *Aggregate exposure* (diet + water). The aggregate exposure of dimethomorph residues for food and drinking water is summarized in Table 4 below. Currently dimethomorph (BAS 550 F) is not considered for residential use and therefore residential exposure was not included in the aggregate exposure assessment.

TABLE 4.—AGGREGATE EXPOSURE OF DIMETHOMORPH (BAS 550 F)

Exposure	Infants (0–1 years)	Children (1–6 years)	Males (20–49 years)	Females (13–49 years)
FOOD				
Acute exposure (mg/kg bwt/day)	0.1736	0.1654	0.06386	0.07306
Chronic exposure (mg/kg bwt/day)	0.007972	0.01512	0.006853	0.007771
%aRfD and %aPAD	NA	NA	NA	NA
%cRfD and %cPAD	7.97	15.12	6.85	7.77
WATER				
Acute exposure (mg/kg/bwt)	0.001265	0.000843	0.000361	0.000402

TABLE 4.—AGGREGATE EXPOSURE OF DIMETHOMORPH (BAS 550 F)—Continued

Exposure	Infants (0–1 years)	Children (1–6 years)	Males (20–49 years)	Females (13–49 years)
Chronic exposure (mg/kg bwt/day)	0.001265	0.000843	0.000361	0.000402
%aRfD and %aPAD	NA	NA	NA	NA
%cRfD and %cPAD	25.30	16.87	7.23	8.03
AGGREGATE				
Acute exposure (mg/kg bwt/day)	0.174865	0.166243	0.064221	0.073462
Chronic exposure (mg/kg bwt/day)	0.009237	0.015963	0.007214	0.008173
%aRfD and %aPAD	NA	NA	NA	NA
%cRfD and %cPAD	33.27	31.99	14.08	15.80

These results indicate the aggregate exposure of dimethomorph (BAS 550 F), from potential residues in food and drinking water, will not exceed EPA's level of concern (100% of RfD). Overall, considering a ''worst-case'' scenario, we can conclude with reasonable certainty that no harm will occur from either acute or chronic aggregate exposure of dimethomorph residues in the current and pending commodities.

3. *Non-dietary exposure.* Currently, there are no registered residential uses for dimethomorph in the United States. Thus, an assessment of non-dietary exposure is not relevant to this petition.

D. Cumulative Effects

There is no information to indicate that any toxic effects produced by dimethomorph would be cumulative with those of any other chemical. The fungicidal mode of action of dimethomorph is unique; dimethomorph inhibits cell wall formation only in Oomycete fungi. The result is lysis of the cell wall that kills growing cells and inhibits spore formation in mature hyphae. This unique mode of action and limited pest spectrum suggest that there is little or no potential for cumulative toxic effects in mammals. In addition, the toxicity studies submitted to support this petition do not indicate that dimethomorph is a particularly toxic compound. No toxic end-points of potential concern were identified.

E. Safety Determination

1. *U.S. population.* Based on the acute toxicity data, BASF believes that dimethomorph does not pose any acute dietary risks. Therefore, a calculation of an acute RfD is not needed. The cPAD is 0.1 mg/kg bwt/day, based on a NOAEL of approximately 10 mg/kg bwt/day (200 ppm) from a 2–year dietary toxicity study in rats that demonstrated decreased body weight and liver foci in females at 750 ppm. The cPAD is calculated using an uncertainty factor of 100. The theoretical maximum residue concentration (TMRC) for all commodities covered in this petition is estimated at 0.003 mg/kg bwt/day for the general population. This represents a dietary exposure to the general population of the United States that is 3.0% of the cPAD. The combined TMRC for all current and pending dimethomorph tolerances in potatoes, tomatoes, grapes, hops, cereal grain commodities, lettuce (head and leaf), endive (escarole), radichio, cucurbit vegetables (crop group 9), bulb vegetables (crop group 3), and fruiting vegetables (except cucurbits) (crop group 8) will utilize less than 10% of the cPAD for the general U.S. population. Since EPA generally has no concern for exposures below 100 percent of the cPAD, EPA should conclude that there is a reasonable certainty that no harm will result from aggregate exposure to dimethomorph residues in or on commodities of the cited crops.

2. *Infants and children.* The TMRC for all commodities covered in this petition is minimal. The consumption of residues of dimethomorph on commodities associated with this request will use approximately 7.0% of the cPAD for children ages 1–6. Moreover, the combined TMRC values for all current and pending dimethomorph tolerances will utilize less than 10% of the cPAD for each of the subgroups. The results of the studies submitted to support this package provide no evidence that dimethomorph caused reproductive, developmental or fetotoxic effects. No such effects were noted at dose levels that were not maternally toxic. The NOAELs observed in the developmental and reproductive studies were 6 to 65 times higher than the NOAEL used to establish the cPAD. There is no evidence to indicate that children or infants would be more sensitive than adults to toxic effects caused by exposure to dimethomorph. Therefore, the registrant believes that the results of the toxicology and metabolism studies support both the safety of dimethomorph to humans based on the intended use as a fungicide on domestically produced fruiting vegetables (except cucurbits) (crop group 8) and the granting of the requested tolerances.

F. International Tolerances.

There are no Canadian, Mexican, or Codex maximum residue levels established for dimethomorph for the commodities associated with this request; consequently, a discussion of international harmonization is not relevant.

[FR Doc. 03–20899 Filed 8–19–03; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0222; FRL–7316–3]

Issuance of Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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