

(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 LD₅₀ studies were conducted on dimethomorph technical:

a. An acute oral toxicity study in the Sprague-Dawley rat for dimethomorph technical with a LD₅₀ 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 LD₅₀ 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 LD₅₀ 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 LD₅₀ 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 LD₅₀ 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 LD₅₀ 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 LC₅₀ 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