

chloro(1,1'-biphenyl)-2-yl) in or on the following raw agricultural and processed commodities of rotational crops: Beet root 1.0 ppm, root vegetables (crop group 1-B) 1.0 ppm, leaves of root and tuber vegetables (crop group 2) 1.0 ppm, head and stem brassica (sub crop group 5-A) 3.0 ppm, leafy brassica greens (sub crop group 5-B) 18.0 ppm, legume vegetables - peas (crop group 6) 2.2 ppm, foliage of legume vegetables (crop group 7): forage 1.5 ppm, hay 2.0 ppm, vines 0.05 ppm, cucurbit vegetables (crop group 9) 1.5 ppm, cereal grains (crop group 15) 0.20 ppm, forage fodder and straw of cereal grains (crop group 16) forage 2.0 ppm, straw 3.0 ppm, fodder 1.5 ppm, grass forage fodder and hay (crop group 17) forage 2.0 ppm, hay 8.0 ppm, straw 0.3 ppm, seed 0.2 ppm, non-grass animal feeds (crop group 18) forage 1.0 ppm, hay 2.0 ppm, seed 0.2 ppm, mint 30.0 ppm, cotton seed 0.05 ppm, cotton gin by-products 0.3 ppm, soybean seed 0.1 ppm, soybean hulls 0.2 ppm, flax seed 3.5 ppm, sunflower seed 3.5 ppm, and rice hulls 0.5 ppm.

BASF Corporation is also proposing to amend 40 CFR part 180 by establishing tolerances for the combined residues of 3-pyridinecarboxamide, 2-chloro-*N*-(4'-chloro (1,1'-biphenyl)-2-yl and its metabolite 2-chloro-*N*-(4'-chloro-5-hydroxy-biphenyl-2-yl)nicotinamide expressed in parent equivalents in the following animal commodities: Cow milk 0.10 ppm, cow muscle 0.10 ppm, cow fat 0.30 ppm, cow meat by-products 0.35 ppm, eggs 0.02 ppm, poultry muscle 0.05 ppm, poultry fat 0.05 ppm, and poultry meat by-products 0.05 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

1. *Plant metabolism.* Nature of the residue studies (OPPTS 860.1300) were conducted in grapes, lettuce, and beans as representative crops in order to characterize the fate of boscalid, also known as BAS 510 F, in all crop matrices. In all three crops, the BAS 510 F Residues of Concern (ROC) were characterized as parent (BAS 510 F). A confined rotational crop study also determined that parent was the residue of concern in the representative crops of radish, lettuce, and wheat.

2. *Analytical method.* In plants the parent residue is extracted using an aqueous organic solvent mixture

followed by liquid/liquid partitioning and a column cleanup. Quantitation is by gas chromatography/mass spectrometry (GC/MS). In livestock the residues are extracted with methanol. The extract is treated with enzymes in order to release the conjugated glucuronic acid metabolite. The residues are then isolated by liquid/liquid partition followed by column chromatography. The hydroxylated metabolite is acetylated followed by a column cleanup. The parent and acetylated metabolite are quantitated by gas chromatography/electron capture detection (GC/ECD).

3. *Magnitude of residues.* Field trials were carried out in order to determine the magnitude of the residue in the following crops: Almonds, beans (dry and succulent), edible peas (dry and succulent), canola, carrot, cucurbits, grape, lettuce, leafy vegetables (brassica and non-brassica), onion (dry bulb and green), peanut, pecan, pepper (bell and chili), pistachio, potato, berries (crop group), stonefruit (cherries, peaches, plums), strawberry, tomato, mint, and sunflower. Field trials were conducted in the United States and Canada in the required regions. Field trials were carried out using the maximum label rate, the maximum number of applications, and the minimum preharvest interval for each crop or crop group. In addition, processing studies were conducted on the following crops to determine concentration factors during normal processing of the raw agricultural commodity into the processed commodities: Canola, grape, peanut, plum, tomato, sunflower, and mint. Magnitude of the residue studies were also carried out in dairy cows and hens. Tier III field rotational crop studies were conducted to support rotational crop tolerances for beet roots, beet tops, cotton, foliage of legume vegetables, soybeans, cereals, grass and non-grass animal feeds. Processing studies were conducted on soybeans and rice to determine concentration factors.

#### B. Toxicological Profile

1. *Acute toxicity.* Based on available acute toxicity data BAS 510 F and its formulated products do not pose acute toxicity risks. The acute toxicity studies place technical BAS 510 F in toxicity category IV for acute oral; category III for acute dermal and category IV for acute inhalation. BAS 510 F is category IV for both eye and skin irritation, and it is not a dermal sensitizer. Two formulated end use products are proposed, a Water Dispersible Granule (WG) termed BAS 510 02 F containing 70% BAS 510 F and a Water Dispersible

Granule (WG) termed BAS 516 02 F containing a 2:1 mixture of BAS 510 F and BAS 500 F. BAS 510 02 F has an acute oral toxicity category of III, acute dermal of III, acute inhalation of IV, eye irritation of III, skin irritation of IV, and is not a dermal sensitizer. BAS 516 02 F has an acute oral toxicity category of III, acute dermal of III, acute inhalation of IV, eye irritation of III, skin irritation of IV, and is not a dermal sensitizer.

2. *Genotoxicity.* Ames Test (one study; point mutation): Negative; *In Vitro* CHO/HGPRT Locus Mammalian Cell Mutation Assay (one study; point mutation): Negative; *In Vitro* V79 Cell Cytogenetic Assay (one study; chromosome damage): Negative; *In Vivo* Mouse Micronucleus (one study; chromosome damage): Negative; *In Vitro* Rat Hepatocyte (one study; DNA damage and repair): Negative. BAS 510 F has been tested in a total of five genetic toxicology assays consisting of *in vitro* and *in vivo* studies. It can be stated that BAS 510 F did not show any mutagenic, clastogenic or other genotoxic activity when tested under the conditions of the studies mentioned above. Therefore, BAS 510 F does not pose a genotoxic hazard to humans.

3. *Reproductive and developmental toxicity.* The reproductive and developmental toxicity of BAS 510 F was investigated in a 2-generation rat reproduction study as well as in rat and rabbit teratology studies.

There were no adverse effects on reproduction in the 2-generation study at any dose tested. Pup effects were observed, with parental toxicity, at the highest dose tested only. In both parental generations, reduced food consumption and reduced body weight (bwt) gain were observed at 10,000 ppm. Both absolute and relative liver weights were increased 21% in F1 generation parental females at the high dose of 10,000 ppm only. Hepatocellular centrilobular hypertrophy (usually slight) was observed in many animals of both sexes in both the F0 and F1 generations at 1,000 ppm, and in all animals of both sexes at 10,000 ppm. Additionally, some of the parental male rats at 10,000 ppm, in both generations, displayed centrilobular liver cell degeneration. Developmental toxicity was seen at 1,000 ppm in the form of decreased pup weights in the F2 males, and at 10,000 ppm in the form of decreased pup weight for both males and females of both the F1 and F2 generations. The parental systemic and developmental toxicity no observed adverse effect levels (NOAEL) are both 100 ppm (12 milligrams/kilogram/day (mg/kg/day)).