UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: 2/13/08

MEMORANDUM

SUBJECT: **Boscalid:** Human Health Risk Assessment to Support Proposed New Uses on Fresh Herbs (Herbs Subgroup 19A), Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, Star Apple and Cotton. PC Code: 128008; Petition Nos: 6E7164, 7F7169; DP Barcodes: 336182, 337369
Regulatory Action: Section 3 Registration Action
Risk Assessment Type: Single Chemical Aggregate

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Attached please find the Human Health Risk Assessment for the active ingredient, boscalid, to support requested new uses on the herbs crop subgroup 19A, various tropical fruits and cotton.

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1.0 Executive Summary

The Interregional Research Project No. 4 (IR-4) has requested the establishment of tolerances for residues of the fungicide, boscalid in/on the herb subgroup 19A, and various tropical fruits to support foliar application to those crops in-field. Concurrently, IR-4 proposes to amend the product label for Pristine® Fungicide (EPA Reg. No. 7969-199) to add the new uses. BASF has requested the establishment of boscalid tolerances in/on cotton resulting from foliar and seed treatment uses. Concurrently, BASF wishes to amend the product label for Pristine® Fungicide to add a foliar use on cotton. In addition the registrant wishes to register BAS 516 ST Seed Treatment Fungicide (EPA File Symbol 7969-EUI) to add a seed treatment use on cotton.

HED notes that, in addition to boscalid, Pristine® Fungicide also contains the active ingredient, pyraclostrobin. This risk assessment addresses only hazards, exposures and risks from the active ingredient, boscalid.

Boscalid is a carboxamide (anilide) fungicide that inhibits mitochondrial respiration, thereby inhibiting spore germination, germ tube elongation, mycelial growth, and sporulation of pathogenic fungi on the leaf surface. Tolerances for residues of boscalid are established under 40CFR §180.589.

Hazard Characterization/Endpoint Selection

The toxicity database for boscalid is complete. Boscalid has a low acute toxicity and is not an eye or skin irritant. The target organs for boscalid are the thyroid and liver.

An acute endpoint was not selected since there were no adverse effects seen in the database, including the developmental toxicity studies, attributable to a single exposure of boscalid. The chronic dietary endpoint, incidental oral endpoint, dermal, and inhalation endpoints were all selected from three co-critical studies, the chronic rat study, the rat carcinogenicity study and a one-year feeding study in dogs. The dose selected for regulation of oral, dermal and inhalation risk at all durations, for all populations is the NOAEL of 21.8 mg/kg/day based on thyroid and hepatic toxicity seen in rats and dogs at higher dose levels. A dermal absorption factor of 15% was derived from an *in vivo* dermal penetration study in the rat. An inhalation absorption factor of 100% was assumed for the inhalation risk assessments.

The standard uncertainty factor of 100 to account for inter- and intra-species variability was applied to all risk assessments. The FQPA safety factor for boscalid was reduced to 1. The boscalid toxicity database is complete; there are no reproductive, developmental or developmental neurotoxic concerns. While the data did show increased quantitative and qualitative sensitivity, the effects noted were either transient or inconsistent or occurred at the limit dose in the presence of maternal toxicity. There are clear NOAELs for these effects and EPA is regulating based on a point of departure below where these effects are seen. Additionally, the estimates of exposure are unlikely to underestimate risk. Therefore, EPA has concluded that the application of an additional safety factor to protect infants and children is not required.

Boscalid is classified as "suggestive evidence of carcinogenicity". Quantification of human cancer risk is not required.

Residue Chemistry Considerations

The nature of the residue in plants, animals and rotational crops is adequately understood for the purposes of this action. Submitted field trial and processing data are adequately supported by storage stability data and were generated using appropriately validated analytical methodology. With the exception of the need for confirmatory data on avocado residues at a 1X rate, adequate field trial and processing studies have been submitted to support the requested uses. An adequate GC/MS method is available to enforce the proposed tolerances.

There are no Codex maximum residue limits (MRLs) established for boscalid. Canada has established MRLs for boscalid, but not for the crops which are the subject of this risk assessment. Therefore there are no issues of international harmonization raised by this action.

Drinking Water Consideration

The proposed new uses have lower total maximum rates than the currently registered turf use. Estimated surface and ground drinking water concentrations (EDWCs) were modeled based on the turf scenario using the screening model FIRST (FQPA Index Reservoir Screening Tool; v.1.10; dated 12/12/2005) and the regression model SCI-GROW (Screening Concentration in Ground Water, v.2.3; dated 7/29/2003), respectively. The chronic, maximum Tier 1 estimated EDWC from surface water was used in the dietary and aggregate risk assessments.

Dietary Exposure and Risk Assessment

A Tier 1 chronic dietary (food and water) risk assessment was conducted which incorporated tolerance level residues, the assumption that all crops were treated, and either data-based or DEEM default processing factors. Boscalid exposure from the existing and newly proposed uses resulted in an estimated risk equivalent to 9.9% of the chronic population adjusted dose (cPAD) for the U.S. population. The most highly exposed subgroup was children 1 – 2 years of age with an exposure which results in an estimated risk equivalent to 33% of the cPAD. Since HED has no concern for risks below 100% of the PAD, there are no chronic dietary concerns based on exposure to the existing and newly proposed uses of boscalid.

Non-Occupational (Residential) Exposure and Risk Assessments

There are no new residential uses associated with this action. Existing residential uses were previously assessed. Application of boscalid by homeowners is not anticipated, so a residential handler assessment was not required. “U-pick” operations and golfing were the two post-application scenarios identified for boscalid. Given the 1-day duration for “U-pick activities, a risk assessment was not required since there are no toxic effects anticipated from a single exposure to boscalid. There are no risks of concern from residential post-application exposure during golfing.

Aggregate Risk Assessments

Short- and Intermediate-Term aggregate risk assessments were conducted for boscalid. The assessments combined average food and water residues with residential exposures. MOEs ranged from 1000 to 1400. The level of concern (LOC) for this assessment is for MOEs that are below 100; therefore, there are no short- and intermediate-term aggregate risks of concern raised by this action.

Since there are no long-term residential exposures for boscalid, the long-term (chronic) aggregate risk assessment includes only average food and water residues and is identical to the chronic dietary risk assessment. There are no long-term aggregate risks of concern for the existing and newly proposed uses of boscalid.

Occupational Exposure and Risk Assessments

Handler and postapplication occupational exposure and risk assessments were conducted for the in-field and seed treatment uses that are the subject of this petition. All occupational handler and post-application MOEs were significantly above the LOC of 100 for these assessments.

The 12-hour REI (reentry interval) appearing on the label is in compliance with the Worker Protection Standard.

Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf

Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the Pesticide Handlers Exposure Database (PHED), have been determined to require a review of their ethical conduct, and have received that review.

Regulatory Recommendation
Provided that the confirmatory data on the magnitude of the residue in avocado are required as a condition of registration, and further provided the petitioner submits a revised Section F as specified in the Residue Chemistry Summary Document cited in this memorandum, this Human Health Risk Assessment supports the registration of the requested new uses and establishment of the following tolerances:

Herbs subgroup 19A, fresh leaves .....40 ppm
Herbs subgroup 19 A, dried……..…….……190 ppm
Dill seed .....140 ppm
Avocado .....1.5 ppm
Sapote, black .....1.5 ppm
Canistel .....1.5 ppm
Sapote, mamey .....1.5 ppm
Mango .....1.5 ppm
Papaya .....1.5 ppm
Sapodilla .....1.5 ppm
Star Apple .....1.5 ppm
Cotton, undelinted seed.....1.0 ppm
Cotton, gin byproducts.....55 ppm

2.0 Ingredient Profile

Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007

Boscalid is a carboxamide (an anilide) fungicide that inhibits mitochondrial respiration, thereby inhibiting spore germination, germ tube elongation, mycelial growth, and sporulation of pathogenic fungi on the leaf surface. Boscalid is currently registered to BASF Corporation as water dispersible granule (WDG) formulations for use on a wide variety of food/feed crops.

2.1 Summary of Proposed New Uses

Table 2.1. Summary of Directions for Use of Boscalid.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Max. Single Applic. Rate (lb ai/A) [1]	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Fresh Herbs (including Angelica, Balm, Basil, Borage, Burnet, Chamomile, Catnip, Chervil, Chive, Chinese Chive, Clary, Coriander (leaf), Costmary, Cilantro (leaf), Curry (leaf), Dillweed (fresh and for processing into oil), Horehound, Hyssop, Lavender, Lemongrass, Lovage (leaf), Marigold, Marjoram (*Origanum* spp.), Nasturtium, Parsley, Pennyroyal, Rosemary, Rue, Sage, Summer Savory, Winter Savory, Sweet Bay, Tansy, Tarragon, Thyme, Wintergreen, Woodruff, and Wormwood)						
Foliar Ground, aerial or through sprinkler irrigation	25.2% WDG [7969-199]	0.29	2	0.58	0	Begin applications prior to the onset of disease development and repeat applications 7 days later as needed, or alternate with another registered fungicide having a different mode of

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						action.
Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, and Star Apple						
Foliar Ground, aerial or through sprinkler irrigation	25.2% WDG [7969-199]	0.29	2	0.58	0	Begin application prior to the onset of disease development and repeat applications 7 days later as needed, or alternate with another registered fungicide having a different mode of action.
Cotton						
Foliar Ground/aerial	25.2% WDG [7969-199]	0.39	2	0.79	30	Begin applications prior to the onset of disease development and continue on a 7-14 day interval.
Seed treatment Slurry or mist type seed treatment equipment	70% WDG [7969-EUI]	0.12 lb ai/ 100 lb seed	1	0.12 lb ai/ 100 lb seed	NA	Apply only in conjunction with labeled rates of mefenoxam-or metalaxyl-containing seed treatment products.

2.2 Structure and Nomenclature

2.3 Physical and Chemical Properties

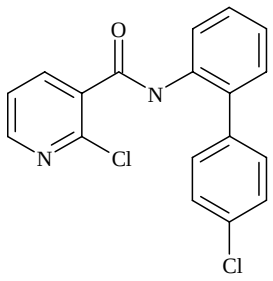
Table 2.2. Test Compound Nomenclature	
Compound	
Common name	Boscalid
Company experimental name	BAS 510 F
IUPAC name	2-chloro-N-(4'-chlorobiphenyl-2-yl)-nicotinamide
CAS name	3-pyridinecarboxamide,2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl
CAS registry number	188425-85-6
End-use product (EPs) requested for registration	Pristine® Fungicide (EPA Reg. No. 7969-199, a WDG formulation containing 12.8% pyraclostrobin + 25.2% boscalid) BAS 516 ST Seed Treatment Fungicide (EPA File Symbol 7969-EUI), a 70% WDG formulation

TABLE 2.3 Physicochemical Properties of Boscalid.		
Parameter	Value	References
Melting point/range	142.8-143.8 C	MRIDs 45404802 and 45404804-45404809
pH	Does not dissociate in water.	
Relative Density (20ºC)	1.381g/cm^3	
Water solubility (20ºC)	4.64 mg/L at pH 6	
Solvent solubility (g/100 mL at 20ºC)	acetone 16-20; ethyl acetate 6.7-8.0 methanol 4-5; 2-propanol <0.01 acetonitrile 4-5; dichloromethane 20-25 toluene 2-5; n-heptane <0.01 1-octanol <0.01; olive oil 2.9 N,N-DMF >25	
Vapor pressure	7 x 10^{-9} hPa	
Dissociation constant, pK_a	None	
Octanol/water partition coefficient, Log(K_{OW})	2.96	
UV/visible absorption spectrum	UV molecular extinction (e[$lmol^{-1}cm^{-1}$]): 3.15 x10^4 at 228 nm; 1.53 x10^3 at 290 nm	

3.0 Hazard Characterization

Boscalid HED HIARC Report, TXR No. 0051613, A. Levy, 3/7/2003
Boscalid Report of the CARC, TXR No. 0051289, J. Kidwell, 11/14/2002
Boscalid Human Health Risk Assessment, DP 290022, Y. Donovan, 9/8/2003
Boscalid Human Health Risk Assessment, DP 327906, L. Hanson, 7/10/2007

The hazard characterization, dose-response and regulatory endpoint selection for boscalid has been discussed in detail in the documents cited above and remain unchanged for this assessment with the exception of the discussion of the FQPA safety factor. Toxicity endpoints are briefly summarized here. Further details on endpoint selection can be found in the documents referenced above. A complete discussion of the FQPA safety factor is contained in Section 3.2 below. This discussion supersedes previous discussion of the FQPA safety factor for boscalid.

3.1 Hazard Characterization/ Endpoint Selection

The toxicity database for boscalid is complete for the purpose of endpoint selection. Boscalid has a low acute toxicity and is not an eye or skin irritant. The target organs for boscalid are the thyroid and liver.

An acute endpoint was not selected for all populations since there were no adverse effects seen in the database, including the developmental toxicity studies, attributable to a single exposure of boscalid.

The chronic dietary endpoint, incidental oral endpoint, dermal, and inhalation endpoints were selected from three co-critical studies, the chronic rat study, the carcinogenicity in rats study and a one-year feeding study in dogs. The dose selected for regulation is the NOAEL of 21.8 mg/kg/day based on thyroid and hepatic toxicity seen in rats and dogs at higher dose levels.

A dermal absorption factor of 15% was derived from an *in vivo* dermal penetration study in the rat. 100% inhalation absorption is assumed for risk assessment purposes.

Boscalid is classified as "suggestive evidence of carcinogenicity". Evidence of carcinogenicity was seen in males (significant trend and pair-wise at the high dose) and in females (trend only), however in both sexes no malignancies were seen. Only benign tumors were observed and these occurred at dose levels above the dose level used to establish the chronic PAD. Additionally, there is no concern for mutagencity. Quantification of human cancer risk is not required.

The endpoints and doses selected for risk assessment purposes are summarized below.

Table 3.1. Summary of Toxicological Doses and Endpoints for Boscalid

Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD/PAD/ LOC	Study and Toxicological Effects
Acute Dietary (All Populations)	No appropriate endpoint attributable to a single dose was available in the current database, including the developmental toxicity studies. Therefore, an acute RfD/acute PAD was not established for any population.			
Chronic Dietary (All Populations)	NOAEL = 21.8 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.218 mg/kg/day Chronic PAD = 0.218 mg/kg/day	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = ~58 mg/kg/day based on liver and thyroid effects
Incidental Oral Short- and Intermediate-Term	NOAEL = 21.8 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	Residential LOC = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = ~58 mg/kg/day based on liver and thyroid effects
Dermal (All Durations)	Oral study NOAEL = 21.8 mg/kg/day DA = 15%	UF_A = 10X UF_H = 10X FQPA SF = 1X	Residential LOC = 100 Occupational LOC = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = ~58 mg/kg/day based on liver and thyroid effects
Inhalation (All Durations)	Oral study NOAEL = 21.8 mg/kg/day IA = 100%	UF_A = 10X UF_H = 10X FQPA SF = 1X	Residential LOC = 100 Occupational LOC = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = ~58 mg/kg/day based on liver and thyroid effects
Cancer	Classified as “suggestive evidence of carcinogenicity”. Quantification of human cancer risk is not recommended.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose. RfD = reference dose. LOC = Level of Concern. DA = dermal absorption. IA = inhalation absorption

3.2 FQPA Uncertainty Factors

The FQPA safety factor has been reduced to 1X for this assessment for the following reasons:

- EPA has a complete toxicity database for boscalid.
- The toxicity studies for boscalid show it generally to have low mammalian toxicity and the database reveals no reproductive, developmental concerns, or developmental neurotoxicity concerns.
- Data involving the testing of young animals did show increased quantitative sensitivity in the young with regard to body weight effects and qualitative sensitivity in one developmental study. However, clear NOAELs were identified for all of these effects. Moreover, the body weight effects at the LOAELs in these studies were either transient or inconsistent and qualitative sensitivity occurred at the limit dose in the presence of maternal toxicity.
- EPA concludes that there are no residual uncertainties for pre and/or post-natal toxicity. The NOAEL used for various risk assessments would address the body weight effects seen at higher doses in the developmental and reproductive studies.
- EPA has conservatively estimated human exposure to boscalid, relying on worst case exposures in food(assuming all registered crops contain residues at the tolerance level), and conservative models as well as pesticide-specific data in estimating exposure from residues in drinking water and from residential uses.

Based on consideration of all of these data, EPA has concluded that is has reliable data showing that infants and children would be safe without application of an additional 10X safety factor.

3.3 Endocrine Disruption

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA has authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, boscalid may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

4.0 Public Health and Pesticide Epidemiology Data

No public health/epidemiology data were used in developing this risk assessment.

5.0 Dietary Exposure/Risk Characterization

5.1 Pesticide Metabolism and Environmental Degradation

5.1.1 Metabolism in Primary Crops

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007
Residue Chemistry Memo DP# 278385, 8/15/03, M. Nelson, (PP# 1F06313)
HED MARC Decision Memo DP# 286786, 1/9/03

The nature of boscalid residues in target (primary) crops is adequately understood, based upon acceptable ^{14}C metabolism studies conducted on grapes, lettuce, and beans. No significant metabolism of boscalid occurred in grapes or lettuce; unchanged parent was the only component identified, accounting for 92-98% and 99% TRR (total radioactive residues), respectively. In bean plants, boscalid metabolized slowly; unchanged parent was the major component identified, accounting for up to 72% TRR in/on bean dry seeds and 99% TRR in/on bean plants; cleavage products 1-(chlorophenyl)-2-aminobenzene and 2-chloronicotinic acid were present in small amounts, accounting for <1% and <10% TRR, respectively.

The HED MARC has concluded that parent boscalid is the sole residue of concern for risk assessment and the tolerance expression for primary (target) crops; the cleavage products were not included based on the limited cleavage which occurred and the low levels of their ingestion expected from dietary and environmental sources.

5.1.2 Metabolism in Rotational Crops

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007
Residue Chemistry Memo DP# 278385, 8/15/03, M. Nelson, (PP# 1F06313)
HED MARC Decision Memo DP# 286786, 1/9/03

The nature of boscalid residues in rotational crops is adequately understood, based upon a ^{14}C confined rotational crop study conducted with three representative crops (radish, head lettuce, and wheat). In lettuce, radish (roots, tops), and wheat (forage,), parent boscalid was the major residue identified (50-96% TRR), with the glucoside metabolite, M510F61, accounting for 1-21% TRR; only parent was identified in wheat grain.

The HED MARC concluded that parent boscalid is the sole residue of concern for risk assessment and the tolerance expression for rotational (inadvertent or indirect residue)

crops; M510F61 was not included based on its being found mainly in feed items and at a relatively low percentage compared to the parent.

5.1.3 Metabolism in Livestock

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007
Residue Chemistry Memo DP# 278385, 8/15/03, M. Nelson, (PP# 1F06313)
HED MARC Decision Memo DP# 286786, 1/9/03

The nature of boscalid residues in livestock is adequately understood based upon acceptable ^{14}C metabolism studies conducted on lactating goat and laying hens. In both the goat and the hen, parent boscalid, M510F 01 (hydroxy metabolite), and M510F 02 (M510F01 glucuronide) were identified as the major residues, with radioactivities >10% TRR; no amide bridge cleavage products were identified.

Based on the structural similarity of boscalid and M510F 01, and the fact that the enzymatic hydrolysis step in the proposed enforcement method will release M510F 02 back to free M510F 01, the MARC concluded that the combined residues of parent BAS 510 F, M510F 01, and M510F02 are the residues of concern for risk assessment and the tolerance expression in livestock matrices.

5.1.4 Analytical Methodology

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007

An adequate GC/MS method (Method D0008) is available for enforcing existing and new tolerances in plant commodities, and an adequate GC/ECD method (Method DFG S19) is available for enforcing existing tolerances in animal commodities.

Residues in/on plant commodities from the field and processing studies associated with these petitions were determined using an LC/MS/MS data collection method (BASF Method D9908). This method was adequately validated in conjunction with the field trial analyses, and the validated limit of quantitation (LOQ) was 0.05 ppm for boscalid in all commodities tested.
The requirements for multiresidue methods (MRM) testing data are fulfilled. Residues of boscalid and its hydroxy metabolite were not adequately recovered using the MRMs.

5.1.5 Environmental Degradation

EFED Drinking Water Assessment, DP 336183, 341459, C. Sutton, 8/8/2007

Boscalid is a persistent compound with low mobility in most soils. The primary degradation pathway is aerobic soil metabolism, which proceeds slowly and results in the formation of intermediates which are relatively rapidly transformed into CO_2 or bound soil residues. Boscalid is stable to hydrolysis and to photolysis on soil and in water. The compound is also not transformed to any significant extent in either aerobic or anaerobic aquatic systems.

5.1.6 Comparative Metabolic Profile

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007
Boscalid HED HIARC Report, TXR No. 0051613, A. Levy, 3/7/2003

In the rat metabolism study, boscalid was readily absorbed orally and was primarily excreted in the feces, with most of the dose being excreted within 24 hours for low doses and 48 hrs for higher doses. Metabolites (hydroxylation and conjugation products) were consistent with Phase I oxidation reactions followed by Phase II conjugation with glucuronic acid or sulfate, or by conjugation of the parent with glutathione with cleavage to sulfate metabolites.

Metabolism of boscalid in other animals (poultry and ruminant) appears to be similar to its metabolism in rats. In both the goat and the hen, parent boscalid, the hydroxy metabolite and the glucuronide were identified as the major residues.

The major residues found in plants were unchanged parent. Cleavage products 1-(chlorophenyl)-2-aminobenzene and 2-chloronicotinic acid were present in small amounts. In rotational corps, the major residue was parent, boscalid with a minor amount of the glucoside metabolite found.

The HED MARC has concluded that parent boscalid is the sole residue of concern for risk assessment and the tolerance expression for primary (target) crops; the cleavage products were not included based on the limited cleavage which occurred and the low levels of their ingestion expected from dietary and environmental sources.

5.1.7 Pesticide Metabolites and Degradates of Concern

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007

The residues of concern to be included in the tolerance expression and for risk assessment purposes are summarized in the table, below.

Table 5.1.7 Summary of Metabolites and Degradates to be included in the Risk Assessment and Tolerance Expression

Matrix		Residues included in Risk Assessment	Residues included in Tolerance Expression
Plants	Primary Crop	Parent only	Parent only
	Rotational Crop	Parent only	Parent only
Livestock	Ruminant	Parent and hydroxy and glucuronic acid metabolites	Parent and hydroxy and glucuronic acid metabolites
	Poultry	Parent and hydroxy and glucuronic acid metabolites	Parent and hydroxy and glucuronic acid metabolites
Drinking Water		Parent only	Not Applicable

5.1.8 Drinking Water Residue Profile

EFED Drinking Water Assessment, DP 336183, 341459, C. Sutton, 8/8/2007

The estimated drinking water concentrations (EDWC) for boscalid in surface water and groundwater were calculated using the screening model FIRST (FQPA Index Reservoir Screening Tool; v.1.10; dated 12/12/2005) and the regression model SCI-GROW (Screening Concentration in Ground Water, v.2.3; dated 7/29/2003), respectively.

The proposed new uses on tropical fruit and herbs have a lower total maximum use rate than the use rate for the previously approved use on turf. Additionally, modeling conducted on cotton indicated that EDWCs from cotton would be well below those determined for turf. Therefore, the EDWCs for turf represent the maximum exposures. EFED has provided updated numbers for turf incorporating a percentage crop area factor. The maximum Tier 1 estimated EDWCs are summarized in the table, below. The surface water value of 0.0296 ppm, which is the highest chronic EDWC, was incorporated into the chronic dietary exposure and risk assessment.

Table 5.1.8 Summary of Estimated Surface Water and Groundwater Concentrations for Boscalid

	Boscalid	
	Surface Water Conc., ppb [a]	Groundwater Conc., ppb [b]
Acute	100.6	0.63
Chronic (non-cancer)	**29.6**	0.63
Chronic (cancer)	Not reported	0.63

[a] From the FIRST (FQPA Index Reservoir Screening Tool; v.1.10; dated 12/12/2005) Tier 1 model. Input parameters are based on application to turf.
[b] From the SCI-GROW (Screening Concentration in Ground Water, v.2.3; dated 7/29/2003)model based on turf application.

5.1.9 Food Residue Profile

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007

The field trial and processing data which serve as the basis for the recommended tolerances and residue levels for the dietary risk assessment are supported by adequate storage stability data and were generated using appropriately validated data collection methods.

The submitted field trial data for basil (fresh) and chives, the representative commodities of Herbs subgroup 19A, along with the data submitted for fresh dill are adequate to support a tolerance of 40 ppm for the Herbs subgroup 19A, fresh leaves. Data submitted for dill seed are adequate to support the required dill seed tolerance of 140 ppm.

The submitted residue data for avocado are inadequate to fulfill data requirements because the field trials were conducted at exaggerated rates. While the submitted data represent an overestimate of the residues expected from the proposed use, the degree of exaggeration can not be determined. Given that the proposed use is for late season foliar application, and includes a 0-day preharvest interval, HED will use the submitted data to

support a tolerance for avocado at 1.5 ppm. The avocado data may be translated to other tropical fruits for which uses are proposed. However, since HED believes that the tropical fruit tolerances may need to be reduced since they will be based on exaggerated rate data; and further, since the avocado data are being translated to support a wide number of tropical/subtropical fruits, HED requests that the petitioner provide additional bridging data. HED recommends the conduct of two or three avocado field trials at the label rates as a condition of registration.

The submitted field trial data for cotton reflecting foliar treatments are adequate and support a tolerance of 1.0 ppm on undelinted seed. However, the cotton field trial data reflecting seed treatment are inadequate because the application rate used was ~0.2x the maximum proposed seed treatment rate. Although the seed treatment study was conducted at <1x, no additional seed treatment data will be required since the bulk of residues are expected to result from foliar uses.

Acceptable processing studies on basil and cotton were submitted. The processing of fresh basil to dried basil resulted in an increase of boscalid residues with an observed average processing factor of 6.3x for dried basil leaves. Based on the highest average field trial value and the average processing factor, the data support a tolerance for the Herbs subgroup 19 A, dried leaves at 190 ppm. The cotton processing study indicates that residues did not concentrate in meal, hulls, crude oil, and refined oil processed from cottonseed bearing detectable residues. The submitted data support a tolerance of 55 ppm in cotton gin byproducts.

Animal tolerances were not reassessed as a result of the proposed new uses as the only feedstuffs associated with proposed uses are undelinted cottonseed, cotton gin byproducts, meal, and hulls. Based on the number of animal feedstuffs with higher tolerances and higher exposure rates, boscalid residues in/on cotton commodities are not expected to contribute substantially to the dietary exposure of livestock.

Adequate confined and limited field rotational crops studies are available, and tolerances for indirect or inadvertent residues have been established based on extensive rotational crop field trials on legume vegetables, cereal grains, grasses, alfalfa, clover, cotton, and root crops. The available data support the 14-day plant-back interval (PBI) on the labels for rotated crops without primary uses of boscalid. There are currently no deficiencies pertaining to rotational crops.

5.1.10 International Residue Limits

There are no Codex maximum residue limits (MRLs) established for boscalid. Canada has established MRLs for boscalid, with identical residue definition as the U.S., but not for the crop commodities discussed in this action review. Therefore, there are no issues of international harmonization raised by these petitions.

5.2 Dietary Exposure and Risk

5.2.1 Acute Dietary Exposure/Risk

Boscalid Chronic Aggregate Exposure and Risk Assessment, DP 336633, D. Davis, 12/13/2007

No toxic effects attributable to a single (i.e., acute) exposure to boscalid have been identified; therefore, an acute reference dose (RfD) has not been established for boscalid and an acute dietary exposure assessment has not been conducted.

5.2.2 Chronic Dietary Exposure/Risk

Boscalid Chronic Aggregate Exposure and Risk Assessment, DP 336633, D. Davis, 12/13/2007

A Tier 1 chronic dietary exposure and risk assessment (food and drinking water) was conducted for boscalid. For food residues, the analysis included tolerance level residues and assumed 100% crop treated. Where data were available, actual processing factors were used in the assessment. In the absence of processing data, DEEM (version 7.81) default factors were used for processed commodities. For drinking water, the highest modeled chronic EDWC was input into the assessment.

Boscalid exposure from the existing and newly proposed uses resulted in an estimated risk equivalent to 9.9% of the chronic population adjusted dose (cPAD) for the U.S. population. The most highly exposed subgroup was children 1 – 2 years of age with an exposure which results in an estimated risk equivalent to 33% of the cPAD. Since HED has no concern for risks below 100% of the PAD, there are no chronic dietary risks of concern as a result of exposure to the established and new uses of boscalid. The results of the chronic dietary risk assessment for all populations are summarized in the table below.

Table 5.2.2 Summary of Dietary (Food and Drinking Water) Exposure and Risk for Boscalid		
Population Subgroup	Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% cPAD*
U. S. Population	0.021623	9.9
All Infants (< 1 year old)	0.049087	22
Children 1-2 years old	**0.071939**	**33**
Children 3-5 years old	0.050548	23
Children 6-12 years old	0.026387	12
Youth 13-19 years old	0.015048	6.9
Adults 20-49 years old	0.016462	7.6
Adults 50+ years old	0.018228	8.4
Females 13-49 years old	0.016662	7.6

5.2.3 Cancer Dietary Risk

Boscalid Chronic Aggregate Exposure and Risk Assessment, DP 336633, D. Davis, 12/13/2007

Boscalid has been classified as "suggestive evidence of carcinogenicity" by the Cancer Assessment Review Committee (CARC) and the CARC has noted that quantification of human cancer risk is not recommended; therefore, a dietary cancer assessment is not required.

6.0 Residential (Non-Occupational) Exposure/Risk Characterization

6.1 Residential Handler Exposure

Boscalid Occupational/Residential Exposure Memorandum, D290072, S. Wang, 6/23/03
Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

There are no new residential (non-occupational) uses proposed for boscalid as a result of the two petitions that are the subject of this risk assessment. The current label specifies that boscalid is to be applied to golf courses only, and is not for use on residential turfgrass or turfgrass being grown for sale or other commercial use such as sod production. Additionally, boscalid is not packaged or marketed for home orchard use. Since the product is not intended for homeowner use, a residential handler exposure and risk assessment is not required.

6.2. Residential Postapplication Exposure

Boscalid Occupational/Residential Exposure Memorandum, D290072, S. Wang, 6/23/03
Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

There are no new residential post application exposure scenarios resulting from the uses proposed in these petitions. Potential non-occupational post application exposure scenarios identified for boscalid based on the established uses include post-application exposure to golfers and persons harvesting fruit at "U-pick" (pick your own) farms and orchards. Exposure can occur during contact with treated golf course turf or while picking strawberries, caneberries, and tree fruit at a "U-pick" facility.

Based on the low vapor pressure of boscalid, the outdoor nature of the uses and the weight of evidence from available residue studies, HED does not anticipate post-application inhalation exposures from the currently approved uses of boscalid.

"U-pick" activities are considered to be "one-time" (<1 day) event. Since no adverse effects were seen in the boscalid toxicity database resulting from a single exposure to the chemical, a post-application exposure and risk assessment is not required for this scenario.

HED conducted a post-application exposure and risk assessment for golfers exposed to treated turf. Duration of exposure is anticipated to be short-term. While BASF did submit a TTR study, due to the methodology used in the study, HED considered it more appropriate to use the standard transfer coefficient of 500 cm^2/hr for golfers. Additionally, the assessment assumed that boscalid would be present on all of the turf through out the course and that the duration of exposure was estimated to be 4 hours. Details of the assessment can be found in the ORE memorandum cited above.

The postapplication dermal MOE for golfers exposed to boscalid is 100,000, which greatly exceeds the level of concern of 100 for this risk assessment. Table 6.2, below summarizes the inputs into the assessment and the exposure and risk to golfers.

Table 6.2 Dermal Post-application Exposure and Risk for Adults and Youth Golfers

Scenario & Product	TTR [1] (ug/cm^2)	CF1 (mg/ug)	Tc [1] (cm^2/hr)	ET (hr/day)	% DA	BW (kg)	Daily Dose [2] (mg/kg/day)	Dermal MOE [3]
Golfing								
BAS 510 02F Turf Fungicide	0.05	0.001	500	4	15	70	0.000214	100,000

TTR is turf transferable residue on day 0 (mg/day). CF1 is unit conversion factor to convert ug units in the TTR to mg for daily exposure (0.001 mg/ug). ET is the exposure time. DA is dermal absorption. BW is body weight. MOE is margin of exposure

1 Based on HED SOP 3.1
2. DD (mg/kg/day) = DFR x CF1 x Tc x ET x %DA/BW
3. Dermal MOE = NOAEL (21.8 mg/kg/day)/ Daily Dose (mg/kg/day)

Golfing is considered a lifetime sport, so individuals of all ages, excluding very small children, routinely play. Children who are 12 years of age or older are likely to represent the vast majority of the youth that play golf on a routine basis. However, the popularity of golf as a recreational pastime has increased steadily over the last few years which has resulted in more young children (i.e., less than 12 years old) becoming involved in the sport. Risk assessments for these children are more difficult to complete because of the increased uncertainties associated with extrapolation of adult dermal exposure data, and because of the increased likelihood of other behaviors that might contribute to exposure, such as mouthing contaminated hands or golf balls. Therefore, the risk associated with children in a golfing scenario is addressed qualitatively in the following discussion.

Five-year-old children were selected as the target group for this exercise because younger children are not believed to be a viable population for the purposes of assessing risk from a golfing scenario. The surface area to body weight ratio (SA/BW) for male children 5 years of age (i.e., the difference is larger for males compared to female making the value more protective) was calculated by using the 95th percentile body surface area and the 50th percentile for body weight. The ratio was intentionally skewed to account for the uncertainties that would be expected with calculating dose levels for children if more definitive data were available, and for potential additional exposure that may occur from mouthing behaviors. This skewed SA/BW for children was compared to that of the average adult, and found to be approximately 70 percent greater. Based on this parameter alone, the child's exposure could be almost twice that of the adult golfer, however, it should be noted that a child is not expected to use the golf course for the same length of time as an adult. While an adult is likely to play a full round of golf (i.e., 18 holes), which takes approximately 4 hours, a child would probably only spend about 2 hours (i.e., the 75th percentile for time spent playing on grass by children aged 1-4 years and 5-11 years) on the course. Thus, the child's shorter duration on the golf course offsets the higher SA/BW, and therefore, the child golfer's exposure is likely to be similar to that of the adult golfer. [Note: The values used to calculate SW/BW and estimate time spent playing on grass were obtained from the EPA Exposure Factors Handbook (1997)].

6.3 Other (Spray Drift, etc.)

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for boscalid. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further

refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

7.0 Aggregate Risk Assessments and Risk Characterization

7.1 Acute Aggregate Risk

No toxic effects attributable to a single (i.e., acute) exposure to boscalid have been identified; therefore, an acute reference dose (RfD) has not been established for boscalid and an acute aggregate risk assessment is not required.

7.2 Short-Term Aggregate Risk

The boscalid short-term aggregate exposure and risk assessments combine average dietary (food and drinking water) exposures with short-term postapplication exposures to adult and youth golfers. MOEs ranged from 1000 to 1400. The level of concern (LOC) for this assessment is for MOEs that are below 100; therefore, there are no short- and intermediate-term aggregate risks of concern. Short-term aggregate risks are summarized in Table 7.2, below.

Table 7.2 Short-Term Aggregate Risk Calculations for Boscalid

Population	Short-Term Scenario					
	NOAEL mg/kg/day	LOC[1]	Max Allowable Exposure[2] mg/kg/day	Average Food & Water Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]
U.S. Population	21.8	100	0.218	0.021622	0.000214	1000
Females (13 – 49 yrs)	21.8	100	0.218	0.016661	0.000214	1300
Adults (50+ yrs)	21.8	100	0.218	0.018227	0.000214	1200
Youth (13 – 19yrs)	21.8	100	0.218	0.01504	0.000214	1400

[1] The LOC includes the standard inter- and intra- species uncertainty factors totaling 100.
[2] Maximum Allowable Exposure (mg/kg/day) = NOAEL/LOC
[3] Residential Exposure = Dermal exposure. Residential exposure value taken from Table 6.2.
[4] Aggregate MOE = [NOAEL/ (avg Food & Water Exposure + residential Exposure)]

7.3 Intermediate-Term Aggregate Risk

There are no intermediate-term residential scenarios; therefore, an intermediate-term aggregate exposure and risk assessment is not required.

7.4 Long-Term Aggregate Risk

There are no long-term residential scenarios for boscalid; therefore the long-term aggregate risk assessment would incorporate only food and drinking water residues. The long-term aggregate risk assessment is identical to the chronic dietary risk assessment for which there are no concerns as shown in Section 5.2.2 of this memorandum.

7.5 Cancer Aggregate Risk

Boscalid has been classified as "suggestive evidence of carcinogenicity" by the Cancer Assessment Review Committee (CARC) and the CARC has noted that quantification of human cancer risk is not recommended; therefore, an aggregate cancer exposure and risk assessment is not required.

8.0 Cumulative Risk Characterization/Assessment

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to boscalid and any other substances and boscalid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that boscalid has a common mechanism of toxicity with other substances.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

9.0 Occupational Exposure/Risk Pathway

The occupational handler exposure and risk assessment is limited to the new uses on herbs, tropical fruit and cotton (foliar and seed treatment) that are the subject of this risk assessment.

Based on the frequency/interval of applications on the agricultural crops and the seasonal nature of seed treatment operation, HED has assumed that handler exposures will be short- or intermediate-term in duration. Since exposure is not expected to be long-term in duration, a long-term handler exposure and risk assessment is not required.

Boscalid has been classified as "suggestive evidence of carcinogenicity" by the Cancer Assessment Review Committee (CARC) and the CARC has noted that quantification of human cancer risk is not recommended; therefore, an occupational handler cancer exposure and risk assessment is not required.

9.1 Short-/Intermediate-Term Handler Risk

Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

The maximum application rates listed on the proposed labels were used for all handler assessments. The average body weight for the general population (70 kg) was used for all assessments.

The handler exposure estimates are based on a central tendency estimate of unit exposure and an upper-percentile assumption for the application rate. The uncertainties in the assessment stem from the use of surrogate exposure data, and assumptions regarding that amount of chemical handled. The estimated exposures are not likely to underestimate risk to occupational handlers.

9.1.1 Handler Exposures and Risks for Crop In-Field Uses

Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

HED identified the seven occupational handler scenarios that would be expected to yield the highest exposure based on the newly requested in-field uses of boscalid. The exposure scenarios assessed are summarized in Table 9.1.1, below.

In the absence of chemical-specific data on human exposure during pesticide handling activities for boscalid, HED used surrogate data from the PHED Version 1.1 to assess exposures. Defaults established by the HED Science Advisory Council for Exposure were used for acres treated per day.

Details of the occupational handler exposure and risk for in-field uses are contained in the memorandum cited above. Occupational handler risks from in-field uses ranged from 300 to 23,000, which exceeds the level of concern (LOC) of 100 for this assessment. Exposures and risks for each scenario are summarized in the table below.

Table 9.1.1 Short-/Intermediate-Term Occupational Exposure and Risk Estimates for In-Field Uses of Boscalid.[1]

Exposure Scenario	Crop	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dose (mg/kg/day)	Total MOE
Mixer/Loader					
Dry Flowables for Ground Application	Tropical Fruit & Herbs	0.0033	0.00026	0.0036	6,100
	Cotton (Foliar)	0.0113	0.00088	0.0122	1800
Dry Flowables for Airblast application	Tropical Fruit & Herbs	0.0016	0.00013	0.0017	13,000
Dry Flowables for Aerial application	Tropical Fruit & Herbs	0.014	0.0011	0.015	1,500
	Cotton (Foliar)	0.0678	0.0053	0.073	300
Applicator					
Sprays with Groundboom	Tropical Fruit & Herbs	0.00070	0.00025	0.00095	23,000
	Cotton (Foliar)	0.0024	0.00084	0.0032	6,800
Sprays with Airblast	Tropical Fruit & Herbs	0.0089	0.00075	0.0097	2,200
Sprays with Fix-Wing Aircraft	Tropical Fruit & Herbs	0.0011	0.000099	0.0012	18,000
	Cotton (Foliar)	0.0051	0.00046	0.0056	3,900
Flagger					
Flagging during Aerial Application	Tropical Fruit & Herbs	0.0024	0.00051	0.0029	7,500
	Cotton (Foliar)	0.0033	0.0007	0.004	5,500

[1]All estimates assume no additional PPE beyond the baseline (long-sleeve shirt, long pants, shoes and socks, no respirator) with the exception of the application by fixed wing aircraft where a closed cockpit is typically employed and reflected in the exposure estimate. The short- and intermediate- dermal NOAEL is 21.8 mg/kg/day from an oral study with 15% dermal absorption. The short- and intermediate- term inhalation NOAEL is 21.8 mg/kg/day with 100% inhalation absorption.

It is understood that human flagging is an uncommon because Global Positioning Satellite (GPS) technology is now predominantly used as indicated by the 2003 National Agricultural Aviation Association (NAAA) survey of their membership. This survey did indicate, however, that human flaggers are still used in approximately 4 percent of aerial

application operations. The Agency will continue to evaluate risks for human flaggers until the potential for exposure is eliminated.

9.1.2 Handler Exposures and Risks for Seed Treatment Use

Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

Four commercial seed treatment handler scenarios were identified that were expected to result in the highest exposures for the proposed seed treatment use on cotton. A complete listing of the exposure scenarios assessed is shown in Table 9.1.2, below.

Handler assessments were based on the unit exposure data from the Science Advisory Council for Exposure (Exposure SAC) Policy #14 (May 1, 2003) and based on the treating/planting data from the Exposure SAC Policy #15 (March 2, 2004).

Details of the occupational handler exposure and risk assessment for the seed treatment use on cotton are contained in the memorandum cited above. Occupational handler risks from the seed treatment application ranged from 1,000 to 6,800 and are above the level of concern of 100 for this risk assessment. Occupational handler exposures and risks for all scenarios assessed for the seed treatment use are summarized in the table below.

Table 9.1.2 Short-/Intermediate-Term Occupational Exposure and Risk Estimates for Seed Treatment Uses of Boscalid.[1]

Exposure Scenario	Crop	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dose (mg/kg/day)	Total MOE
Loader/Applicator					
Loading/Applying Liquids for Seed Treatment	Cotton	0.0095	0.00093	0.010	2,200
Sewer					
Sewing Seeds after Seed Treatment	Cotton	0.0026	0.00063	0.0032	6,800
Bagger					
Bagging Seeds after Seed Treatment	Cotton	0.0037	0.00044	0.0041	5,300
Multiple Activities Worker					
Multiple Activities for Seed Treatment	Cotton	0.017	0.0044	0.021	1,000

[1]Loader/Applicator and Multiple Activities Worker assessments assume single layer of clothing and gloves. Sewer and Bagger assessments assume single layer of clothing, no gloves. The short- and intermediate-dermal NOAEL is 21.8 mg/kg/day from an oral study with 15% dermal absorption. The short- and intermediate- term inhalation NOAEL is 21.8 mg/kg/day with 100% inhalation absorption.

9.1.3 Secondary Handler Risks from Seed Treatment Uses

Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

A "secondary handler" assessment was conducted for the seed treatment use of boscalid. The scenario consists of the farmer purchasing bags of treated seed, placing the seed in the hopper, and applying seed to fields. Secondary handler's exposure associated with seed treatment was calculated using unit exposures given from the Science Advisory Council for Exposure Policy #14 (May 1, 2003). For cotton, it was assumed that 3,600 lbs of seed per day could be planted. The details of the assessment are contained the memorandum cited above. The MOE for the scenario is 8,700 as shown in table 9.1.3 and is not of concern.

Table 9.1.3 Short-Term Occupational "Secondary Handler" Exposure and Risk Estimates for Seed Treatment Uses of Boscalid.[1]

Exposure Scenario	Crop	Daily Dermal Dose (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Combined Daily Dose (mg/kg/day)	Total MOE
Post-application: planting seeds in the field	Cotton	0.0023	0.00021	0.0025	8,700

[1]All estimates assume single layer of clothing and gloves. The short- and intermediate- dermal NOAEL is 21.8 mg/kg/day from an oral study with 15% dermal absorption. The short- and intermediate- term inhalation NOAEL is 21.8 mg/kg/day with 100% inhalation absorption.

9.2 Short-Term Postapplication Risks

Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

Postapplication exposure and risk assessments used the maximum proposed use rates. Assessments assumed a body weight of 70 kg and that workers could be exposed for 8 hrs a day. For the postapplication risk assessments, the duration of exposure was assumed to be less than 30 days per year (short-term).

9.2.1 Post Application Exposures and Risks from In-Field Uses

Occupational and Residential Exposure/Risk Assessment for Boscalid, D336634, S. Wang, 11/2/07

Occupational postapplication exposure scenarios that were assessed for the in-field uses of boscalid that are the subject of this action are summarized in Table 9.2.1, below. Transfer coefficients were taken from the Science Advisory Council for Exposure Policy Number 3 and the exposure and risk assessment were conducted for "0-day" exposures. MOEs ranged from 650 to 20,000 and are not of concern since they exceed the LOC of 100 for this assessment. Post application exposures and risks resulting from the in-field uses of boscalid are summarized in the table below.

Table 9.2.1 Post-application Exposure and Risk for In-Field Uses

Crop	Application Rate (lb ai/A)	Work Activity	Transfer Coefficients[a] (cm^2/hr)	Post-application Day[b]	DFR[c] (µg/cm^2)	Daily Dose[d] (mg/kg/day)	MOE [e]
Herbs	0.29	irrigation, scouting, thinning, weeding immature plants	500	0	0.651	0.0056	3,900
		irrigation, and scouting mature plants	1500	0	0.651	0.0167	1,300
		hand harvesting, pruning, thinning mature plants	2500	0	0.651	0.0279	780
Tropical Fruits	0.29	propping	100	0	0.651	0.0011	20,000
		irrigation, scouting, hand weeding	1000	0	0.651	0.011	2,000
		harvesting	1500	0	0.651	0.017	1,300
		thinning	3000	0	0.651	0.033	650
Cotton	0.4	irrigation, scouting	100	0	0.898	0.0015	14,000
		irrigation, and scouting thinning, weeding immature/low plants	1500	0	0.898	0.0231	940

a Transfer coefficient from Science Advisory Council for Exposure: Policy Memo #003 "Agricultural Transfer Coefficients," 05/07/98.

b Day after treatment represents approximately 12 hours following application when sprays have dried.

c DFR = Application Rate (lb ai/acre) x Fraction of active ingredient that remains on the foliage when sprays have dried x 4.54E8 µg/lb x 24.7E-9 acre/cm^2.

d Daily dose = DFR (µg/cm^2) x TC (cm^2/hr) x conversion factor (1 mg/1,000 µg) x exposure time (8 hrs/day) x dermal absorption (0.15) / body weight (70 kg).

e MOE = NOAEL (21.8 mg/kg/day) / daily dose (mg/kg/day).

9.3 Worker Protection Standard

The technical material has a Toxicity Category IV for eye irritation/skin irritation, and a Category III for acute dermal Toxicity. Per the Worker Protection Standard (WPS), a 12-hr restricted entry interval (REI) is required. The 12 hour REI appearing on the labels is appropriate.

10.0 Data Needs and Label Recommendations

10.1 Toxicology

The toxicology database for boscalid is complete. No new data on the toxicity of boscalid are required to support the requested new uses.

10.2 Residue Chemistry

Boscalid Residue Chemistry Summary Chapter, DP 336632, C. Olinger, 11/27/2007

The following residue chemistry data are required to support the requested new uses:

- Additional avocado field trial studies at the label maximum rate are required to bridge the submitted exaggerated rate studies. These data are considered confirmatory and can be required as a condition of the registration of boscalid on tropical fruits.

- The petitioner should submit a revised Section F to incorporate the recommended commodity definitions and tolerances specified in the Residue Chemistry Summary Chapter cited above.

10.3 Occupational and Residential Exposure

No new occupational or residential exposure information is required to support the requested new uses.

11.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the USDA under the Continuing Survey of Food Intakes by Individuals (CSFII) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

12.0 Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the Pesticide Handlers Exposure Database (PHED), have been determined to require a review of their ethical conduct, and have received that review.

References

BAS 510 F: Report of the Cancer Assessment Review Committee, TXR No. 0051289, J. Kidwell, 11/14/2002.

BAS 510 F- Report of the Hazard Identification Assessment Review Committee, A. Levy, TXR No. 0051613, 3/7/2003.

Boscalid. Petitions for the Establishment of Permanent Tolerances on: (i) Fresh Herbs (Herbs Subgroup 19A), Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, and Star Apple - PP#6E7164; and (ii) Cotton Commodities - PP#7F7169. Summary of Analytical Chemistry and Residue Data, DP 336632 and 338785, C. Olinger, 11/27/2007.

Drinking Water Assessment for the IR-4 Petition for the Use of Boscalid on Tropical Fruits and Fresh Herbs, and a Proposed New Use on Cotton, DP 336183 and 341459, C. Sutton, 8/8/2007.

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