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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM:

Date: 5/5/2005

Subject: ID#04CA21 - Section 18 Exemption for the use of Boscalid on Tangerines in California

DP Barcode: D309981

Decision Number: 349561

PC Code: 128008

Trade Name: Pristine

Class: Fungicide

40 CFR: 180.589

EPA Reg. Number: 7969-199

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1

JUN 20 2005

Introduction

The State of California Department of Pesticide Regulation (California DPR) has requested an emergency exemption for the use of boscalid on tangerines in California for control of *Alternaria alternata* (alternaria rot, black rot, or late blight). This is the first Section 18 request for this use. The request entails application of 5,900 lbs of the active ingredient (ai) to 5,000 acres of land between October 1, 2004 and January 31, 2005.

Agency Memoranda Used to Support this Section 18 Exemption Risk Assessment

PP#s 1F06313. Human Health Risk Assessment for New Fungicide BAS 510 F (Common Name: Boscalid) – Proposal for Tolerances for Residues in/on Numerous Crops and Livestock Commodities. D290022, Y. Donovan, *et al.*, 9/8/03.

PP#s 2F6434 and 3F6580. Human Health Risk Assessment for Boscalid. Proposal for Tolerances for Residues in/on Soybeans, Pome Fruit, and Hops. D297935, D. Dotson and S. Wang, 2/10/04.

Hazard Identification Assessment Review Committee Report, 3/7/03. TXR No. 0051613.

Boscalid Chronic Dietary Exposure Assessment for the Section 18 Registration Action on Tangerines in California, D316141, D. Dotson, 5/5/05.

ORE Assessment: Occupational and Residential Exposure/Risk Assessment for Use of BAS 510F on Potatoes, Bulb Vegetables, Lettuce, Dry/Succulent Beans, Fruiting Vegetables, Stone Fruits, Small Berries, Tree Nuts, Pistachio, Grapes, Strawberries, Peanuts, Canola, Brassica Leafy Vegetables, Cucurbits, Edible Peas, Mint, Root Vegetables, Sunflower, and Golf Course Turfgrass, D290072, S. Wang, *et al.*, 6/23/03.

EFED Water Memo: Section 18 for Boscalid to control fungal disease caused by *Alternaria alternata* on mandarin oranges in California, D309982, C. Salice, 4/27/05.

Assessment Summary

General Information

Tolerances have been established for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl) in/on a wide variety of crops and animal commodities. Tolerances on primary crops range from 0.05 ppm on the Tuberous and Corm Vegetable Crop Subgroup (1C) to 30 ppm on peppermint and spearmint tops. Tolerances on rotational crops range from 0.05 ppm on several commodities to 8.0 ppm on grasses. Animal commodity tolerances range from 0.02 ppm for eggs to 0.35 ppm for the meat byproducts of cattle, goats, horses, and sheep. Boscalid is a member of the carboxamide (anilide) class of compounds. In target crops and

rotational crops, parent boscalid is the only residue of concern for both tolerance expression and risk assessment. In animal commodities, parent boscalid, a hydroxy metabolite, and the glucuronide of the hydroxy metabolite are the residues of concern for tolerance expression and risk assessment. In drinking water, parent boscalid is the only residue of concern for risk assessment.

The first human health risk assessment for boscalid (formerly BAS 510 F) was completed on 9/8/2003 by Y. Donovan, *et al.* (D290022). The Health Effects Division (HED) recommended in favor of the establishment of tolerances on a number of plant and animal commodities. There have been no additions to the toxicological database, and no changes in either the toxicological endpoints chosen for hazard evaluation or the FQPA Safety Factor determination. Therefore, reference may be made to the initial risk assessment for information pertaining to the toxicological and residue chemistry databases.

Proposed Use

The proposed use directions specify a maximum application rate of 18.5 oz product (0.292 lbs boscalid) per acre, a maximum of 4 applications per season, application intervals of 10 to 21 days, no more than two sequential applications of the product before alternating to a fungicide with a different mode of action, and a PHI of 0 days.

Toxicology

As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD) for the general population or females 13-50 years old. An acute aggregate risk assessment is not needed. Chronic toxicity was seen in several species of animals. Effects were seen in the thyroid and liver. The chronic NOAEL was 21.8 mg/kg bw/day. The FQPA Safety Factor was reduced to 1x and the uncertainty factor for intraspecies variability and interspecies extrapolation was 100x. As a result, the chronic population adjusted dose was 0.218 mg/kg/day. For the dermal route, the absorption rate was 15% relative to oral. For the inhalation route, the absorption rate was assumed to be 100%. The residential and occupational level of concern (LOC) for all routes is an MOE of 100. The Cancer Assessment Review Committee (CARC) classified boscalid as having "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." The quantification of human cancer risk was therefore not recommended.

Occupational Exposure

There are 2 handler scenarios that are expected to result in the highest exposure for the proposed uses: (1) mixing/loading dry flowable for air-blast applications, and (2) applying sprays with air-blast equipment. MOEs for the handlers were greater than the target of 100 at the baseline level (13,000 and 2,200).

Dietary Exposure

An acute dietary endpoint was not identified for boscalid. The chronic dietary exposure analysis was based on tolerance level residues and 100% crop treated assumptions. DEEM (Version 7.81) default processing factors were used for some commodities. The general U.S. population and all population subgroups had risk estimates that were below HED's level of concern (i.e., 100% of the chronic population adjusted dose (cPAD)). As such, this analysis is a very conservative one. The cPAD value for the most highly exposed population subgroup (Children 1-2 years) is 26%, and that for the general U.S. population is 7%.

Drinking Water Exposure Estimates

EFED provided estimated drinking water concentrations (EDWCs) for the use of boscalid on tangerines. The estimated surface water concentration is 15 ppb and the estimated groundwater concentration is 0.5 ppb. In the previous water analysis performed by EFED (for the use of boscalid on soybeans, pome fruit, and hops), higher EDWCs were provided because the assessment was based on the commodity with the highest application rate, turf. For this Section 18, the previous numbers will be used in order to be conservative, and protective of human health. The chronic surface water value based on the use on turf is 26 ppb and the groundwater value is 0.6 ppb.

Non-Dietary, Non-Occupational Exposure

The non-occupational/residential exposure/risk assessment is based on HED's first ORE assessment for boscalid. A golfing scenario is evaluated in this assessment. The MOEs for dermal post-application exposure for golfing are all greater than the target MOE of 100 and therefore do not exceed HED's level of concern.

Aggregate Risk

As there is no acute endpoint, an acute aggregate risk assessment was not performed.

The short-term aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and non-occupational uses (golf courses). Postapplication exposures from the proposed use on golf courses is considered short-term, and applies to adults and youths. Short-term aggregate risk does not exceed HED's level of concern for exposure of adults and youth to boscalid residues.

As no intermediate-term non-occupational exposures are anticipated, an intermediate-term aggregate risk assessment is not needed.

Chronic aggregate (food + water) exposure to boscalid is below HED's level of concern for the general U.S. population and all population subgroups. Dietary (food only) exposure for the most highly exposed population subgroup (Children 1-2 years) utilizes 26% of the cPAD, and results in a chronic DWLOC of 1,600 ppb. As the chronic EEC of 26 ppb is less than the chronic

DWLOCs for the general U.S. population and all population subgroups, aggregate chronic exposure does not exceed HED's level of concern.

Cumulative Risk

HED does not have, at this time, available data to determine whether boscalid has a common mechanism of toxicity with other substances, or how to include this pesticide in a cumulative risk assessment. For the purposes of this Section 18 exemption, HED has assumed that boscalid does not interact with other pesticides to produce a cumulative effect.

Tolerance Harmonization

There are no established Codex, Mexican, or Canadian maximum residue limits for boscalid in/on tangerines. As a result, harmonization of tolerances is not an issue for this Section 18.

Conclusions

For the proposed use of boscalid on tangerines in California, aggregate risk estimates are below HED's level of concern for all non-occupational exposure scenarios. The estimated occupational exposures are below HED's level of concern assuming a restricted entry interval of not less than 12 hours is established for the proposed use. **HED has no concerns that would preclude the establishment of a time-limited tolerance for this Section 18 exemption of 2.0 ppm for residues of boscalid in/on tangerine.**

Toxicological Considerations

The toxicological database is complete for purposes of this Section 18 exemption. The database was evaluated by HED's HARC on September 5, 2002 and January 23, 2003 (TXR Number 0051613, 3/7/03). The toxicology database was characterized in HED's Risk Assessment for the use of boscalid on various crops and livestock commodities (Memo, D290022, Y. Donovan, 9/8/2003). Toxicological endpoints for boscalid are summarized in Table 1.

The hazard assessment was summarized in the previous risk assessment. As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute-dietary risk to the general population or to the subpopulation females 13-50 years old. Therefore, there is no acute reference dose (aRfD) or acute population-adjusted dose (aPAD) for the general population or females 13-50 years old. An acute aggregate risk assessment is not needed.

Chronic toxicity was seen in several species of animals. Effects were seen in the thyroid and liver. The chronic NOAEL was 21.8 mg/kg bw/day. The FQPA Safety Factor was reduced to 1x and the uncertainty factor for intraspecies variability and interspecies extrapolation was 100x. As a result, the chronic population adjusted dose was 0.218 mg/kg/day. For the dermal route, the absorption rate was 15% relative to oral. For the inhalation route, the absorption rate was assumed to be 100%. The residential and occupational level of concern (LOC) for all routes is an MOE of 100. The Cancer Assessment Review Committee (CARC) classified boscalid as

having “suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.” The quantification of human cancer risk was therefore not recommended.

Table 1. Summary of Toxicological Doses and Endpoints for Boscalid			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	No appropriate endpoint identified	NA	NA
Chronic Dietary (All populations)	NOAEL= 21.8 UF = 100 Chronic RfD = 0.218 mg/kg/day	FQPA SF = 1 cPAD = <u>chronic RfD</u> FQPA SF = 0.218 mg/kg/day	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Incidental Oral (Short and intermediate term residential only)	NOAEL= 21.8 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Dermal (All Durations)	Oral study NOAEL=21.8 mg/kg/day (dermal absorption rate = 15%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Inhalation (All Durations)	Oral study NOAEL= 21.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic rat, carcinogenicity rat and 1-year dog studies LOAEL = 57-58 mg/kg/day based on liver and thyroid effects
Cancer (oral, dermal, inhalation)	Classification: “Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential.”		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

Occupational Exposure Considerations

Use Profile

The State of California Department of Pesticide Regulation has requested an emergency exemption for the use of boscalid on tangerines in California for control of *Alternaria alternata* (alternaria rot, black rot, or late blight). This is the first Section 18 request for this use. The request entails application of 5,900 lbs of the active ingredient (ai) to 5,000 acres of land between October 1, 2004 and January 31, 2005.

The proposed use directions specify a maximum application rate of 18.5 oz product (0.292 lbs boscalid) per acre, a maximum of 4 applications per season, application intervals of 10 to 21 days, no more than two sequential applications of the product before alternating to a fungicide with a different mode of action, and a PHI of 0 days.

Table 2: Summary of Use Pattern and Formulation Information					
Formulation	Application Methods	Use Site	Application Rate (lb ai/A)	Frequency of Application	Application Interval
Pristine Fungicide	Ground	tangerines	0.292	4 applications	10-21 days

Handlers

Equations/Calculations:

The following equations were used to calculate handler exposure and risk:

$$\text{Dermal Dose (mg/kg/day)} = \frac{\text{Rate (lb ai/A)} \times \text{UE (mg/lb ai)} \times \text{DA} \times \text{Acres Treated (A/day)}}{\text{BW (kg)}}$$

$$\text{Inhalation Dose (mg/kg/day)} = \frac{\text{Rate (lb ai/acre)} \times \text{UE (mg/lb ai)} \times \text{Acres Treated (A/day)}}{\text{BW (kg)}}$$

Where:

Rate (Application Rate)	=	Maximum application rate on product label (lb ai/acre)
UE (Unit Exposure)	=	Exposure value derived from August 1998 PHED Surrogate Exposure Table (mg/lb ai handled)
DA (dermal absorption factor)	=	Factor to account for dermal absorption (15%) when endpoint is selected from an oral study.
Acres Treated	=	Maximum number of acres treated per day (acres/day)
BW	=	Body weight (kg)

$$\text{Combined Daily Dose (mg/kg/day)} = \text{Dermal Dose (mg/kg/day)} + \text{Inhalation Dose (mg/kg/day)}$$

$$\text{MOE} = \frac{\text{NOAEL (21.8 mg/kg/day)}}{\text{Combined Daily Dose (mg/kg/day)}}$$

Exposure Scenarios:

There are 2 handler scenarios that are expected to result in the highest exposure for the proposed uses:

- Mixing/Loading Dry Flowable for Air-Blast Applications (Scenario 1)
- Applying Sprays with Air-Blast Equipment (Scenario 2)

Application Rate:

The maximum application rate listed on the proposed label provided by the Registration Division was used for all exposure assessments. The maximum rate is 0.29 lb ai/A.

Area or the Amount Treated:

Based on HED's Exposure Science Advisory Council Policy Number 9.1, 40 acres/day for applications on tree crops using air blast equipment were assumed.

Body Weight:

The average body weight for general population (70 kg) was used for all assessments.

Exposure Frequency:

No data on the number of exposure days per year were provided. For this risk assessment it was assumed that handlers would be exposed for less than 6 months per year. Long-term exposure is not expected.

Unit Exposures:

The unit exposures are based on the Pesticide Handler's Exposure Database (PHED) Version 1.1 as presented in the August 1998 PHED Surrogate Exposure Guide. PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts—a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer

algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides is primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled, resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure" value representing the entire body.

There are three basic risk mitigation approaches considered appropriate for controlling occupational exposures. These include administrative controls, the use of personal protective equipment or PPE, and the use of engineering controls. Occupational handler exposure assessments were completed by HED using baseline, PPE, and engineering controls. [Note: Administrative controls available generally involve altering application rates for handler exposure scenarios. These are typically not utilized for completing handler exposure assessments.] The baseline clothing level scenario for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, no chemical resistant gloves, and no respirator. The first level of mitigation generally applied is PPE. As reflected in the calculations included herein, PPE may involve the use of an additional layer of clothing, chemical-resistant gloves, and a respirator. The next level of mitigation considered in the risk assessment process is the use of appropriate engineering controls which, by design, attempt to eliminate the possibility of human exposure. Examples of commonly used engineering controls include enclosed tractor cabs and cockpits, closed mixing/loading/transfer systems, and water-soluble packets.

Handlers' Exposure and Risk:

MOEs for the handlers were greater than the target of 100 at the baseline level (13,000 & 2,200). Summaries of the risks for handlers are presented in Table 3.

The handler exposure estimates in this assessment are based on a central tendency estimate of unit exposure and an upper-percentile assumption for the application rate, and are assumed to be representative of high-end exposures. The uncertainties associated with this assessment stem from the use of surrogate exposure data (e.g., differences in use scenario and data confidence),

and assumptions regarding that amount of chemical handled. The estimated exposures are believed to be reasonable high-end estimates based on observations from field studies and professional judgement.

Table 3. Non-Cancer Risk for Boscalid Handlers

Exposure Scenario (Scenario #)	Mitigation Level ^a	Dermal Unit Exposure ^b (mg/lb ai)	Inhalation Unit Exposure ^c (ug/lb ai)	Crop	Application Rate (lb ai/A)	Amount Treated ^d (A/day)	Daily Dermal Dose ^e (mg/kg/day)	Daily Inhalation Dose ^f (mg/kg/day)	Combined Daily Dose ^g (mg/kg/day)	MOE ^h
Mixer/Loader										
Dry Flowables for Air Blast application (1)	Baseline	0.066	0.77	Mandarin oranges & Mandarin hybrids	0.29	40	0.0016	0.00012	0.0017	13,000
Applicator										
Sprays with Air Blast (2)	Baseline	0.36	4.5	Mandarin oranges & Mandarin hybrids	0.29	40	0.0089	0.00075	0.0097	2,200

- a Baseline consists of long-sleeve shirt, long pants, shoes, and socks and no respirator. PPE consists of long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and no respirator.
- b Baseline Dermal Unit Exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractors, as appropriate.
- c Baseline Inhalation Exposure represents no respiratory protection, open mixing/loading, and open cab tractors, as appropriate.
- d Daily acres treated values are from EPA estimates of acreage that could be treated or volume handled in a single day for each exposure scenario of concern, based on the application method and formulation/packaging type.
- e Daily dermal dose (mg/kg/d) = [unit dermal exposure (mg/lb ai) * dermal absorption (0.15) * application rate (lb ai/acre) * daily acres treated / body weight (70 kg).
- f Daily inhalation dose (mg/kg/d) = (unit exposure (ug/lb ai) * (1 mg/1000 ug) conversion * appl. rate (lb ai/acre) * daily acres treated / body weight (70 kg).
- g Combined daily dose = daily dermal dose + daily inhalation dose.
- h MOE = NOAEL (21.8 mg/kg/d) / combined daily dose. UF = 100.

Post-application

Equations/Calculations:

The following equations were used to calculate post-application exposure and risk:

$$\text{Daily dermal dose,} = \frac{\text{DFR}_t (\mu\text{g}/\text{cm}^2) \times 1\text{E-3 mg}/\mu\text{g} \times \text{Tc (cm}^2/\text{hr)} \times \text{DA} \times \text{ET (hrs)}}{\text{BW (kg)}}$$

Where:

- t = number of days after application day (days)
- DFR_t = dislodgeable foliage residue on day "t" (μg/cm²)
- Tc = transfer coefficient (cm²/hr)
- DA = dermal absorption factor (unitless)
- ET = exposure time (hr/day)

BW = body weight (kg)

$$DFR_t (\mu\text{g}/\text{cm}^2) = AR (\text{lb ai}/\text{acre}) \times F \times (1-D)^t \times 4.54\text{E}8 \mu\text{g}/\text{lb} \times 24.7\text{E}-9 \text{ acre}/\text{cm}^2$$

Where:

Rate = application rate (lb ai/acre)

F = fraction of ai retained on foliage or 20% (unitless)

D = fraction of residue that dissipates daily or 10% (unitless)

Post-application Activities and Transfer Coefficients:

Anticipated post-application activities and their respective dermal transfer coefficients (TCs) are summarized in Table 4. The information in the table is based on the Science Advisory Council for Exposure Policy Number 3.1 and is based on proprietary and non-proprietary data.

Application Rate:

The maximum application rate listed on the proposed label provided by the Registration Division was used for all assessments. The maximum rate is 0.29 lb ai/A.

Exposure Frequency:

No data on the number of exposure days per year was provided. For this risk assessment, it was assumed that post-application workers would be exposed for less than 30 days per year.

Exposure Duration:

Workers were assumed to be exposed 8 hours per day.

Body Weight:

The average body weight of an adult (70 kg) was assumed.

Table 4. Anticipated Post-application Activities and Dermal Transfer Coefficients

Proposed Crops	Policy Crop Group Category	Exposure Potential	Transfer Coefficients (cm ² /hour)	Activities
Oranges	Evergreen Tree Fruit	Very Low	100	propping
		Low	1000	irrigation, scouting, hand weeding
		Medium	3000	harvesting, pruning, training, tying, thinning
		High	8000	harvesting, thinning, pollination, bagging, tying, misc. hand labor

Post-application Exposure and Risk:

A summary of the post-application exposures/risks is presented in Table 5. All MOEs calculated for post-application activities on the day of application exceeded the target MOE of 100 and therefore are not a concern to HED.

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.

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
Oranges	0.29	propping	100	0	0.651	0.0011	20,000
		irrigation, scouting, hand weeding	1000	0	0.651	0.011	2,000
		harvesting, pruning, training, tying, thinning	3000	0	0.651	0.033	650
		harvesting, thinning, pollination, bagging, tying, misc. hand labor	8000	0	0.651	0.089	240

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 $DFR = \text{Application Rate (lb ai/acre)} \times \text{Fraction of active ingredient that remains on the foliage when sprays have dried} \times 4.54E8 \mu\text{g/lb} \times 24.7E-9 \text{ acre/cm}^2$.

d $\text{Daily dose} = DFR (\mu\text{g/cm}^2) \times TC (\text{cm}^2/\text{hr}) \times \text{conversion factor} (1 \text{ mg}/1,000 \mu\text{g}) \times \text{exposure time} (8 \text{ hrs/day}) \times \text{dermal absorption} (0.15) / \text{body weight} (70 \text{ kg})$.

e $MOE = NOAEL (21.8 \text{ mg/kg/day}) / \text{daily dose} (\text{mg/kg/day})$.

Residue Chemistry Considerations

Nature of the Residue

In target crops and rotational crops parent boscalid is the only residue of concern for both tolerance expression and risk assessment. In animal commodities, parent boscalid, a hydroxy metabolite, and the glucuronide of the hydroxy metabolite are the residues of concern for tolerance expression and risk assessment. In drinking water parent boscalid is the only residue of concern for risk assessment.

Analytical Methods

The data collection method for plants and the tolerance enforcement method have been summarized in a previous residue chemistry summary document (PP# 1F6313, D278385, M. Nelson, 8/15/03). The data collection method for plants, Method D9908 (MRID 45405027) determines residues of boscalid in plant matrices. Residues are extracted with an aqueous organic solvent mixture followed by liquid/liquid partitioning and column clean-up. Quantitation of boscalid is by LC/MS/MS, using the positive ionization mode to monitor ion transitions from m/z 343 to 307 for boscalid. Quantitation is obtained using an external calibration curve of boscalid standards. The validated limit of quantitation (LOQ) is reported to be 0.05 ppm for residues of boscalid in/on plant matrices. Provided concurrent method validations are conducted in conjunction with field samples, this method is considered to be acceptable for data collection purposes.

A separate GC/MS method (Method D0008) is the enforcement method for residues of boscalid in/on plant matrices. The Analytical Chemistry Branch in BEAD concluded that the method is acceptable for enforcement purposes in plants without the need for an EPA validation (8/12/03, D. Swineford and E. Kolbe, D284510). An enforcement method is also available for the residues of concern in livestock. Method DFG S19 is based on GC with electron capture detection and was successfully validated by ACB/BEAD (7/17/03 Memo, D. Swineford and E. Kolbe).

The multiresidue methods (MRMs) have been summarized in a previous residue chemistry summary document (PP# 1F6313, D278385, M. Nelson, 8/15/03). Residues of boscalid and its hydroxy metabolite were not adequately recovered using the MRMs.

Magnitude of the Residue

To support the Section 18 Emergency Exemption, the California Citrus Quality Council submitted to the California DPR the final report of a BASF residue study titled "Magnitude of BAS 500 02 F and BAS 510 02 F Residues on Citrus" (Record Number 213546). The study contained the results of field trials performed on oranges, grapefruit, and lemons. There were 13 orange trials (24 samples), 6 grapefruit trials (12 samples), and 5 lemon trials (10 samples). The orange trials were conducted in Florida (8 trials), California (3 trials), and Texas (1 trial). The grapefruit trials were conducted in Florida (3 trials), California (2 trials), and Texas (1 trial). The lemon trials were conducted in Florida (1 trial), California (2 trials), and Arizona (2 trials). In oranges residues ranged from 0.18 to 1.43 ppm, in grapefruit residues ranged from 0.1 to 0.85 ppm, and in lemons residues ranged from 0.6 to 1.51 ppm. For the field trials, the maximum application rate and minimum PHI were used. Table 6 provides specific information concerning the field trials.

Table 6. Summary of Residue Chemistry Considerations		
Parameter	Proposed Use	Residue Data
Chemical	Boscalid	Boscalid
Formulation	Pristine Fungicide	Pristine Fungicide
Crop	Tangerines	Oranges, Grapefruit, Lemons
Type of Application	Ground	Not Specified
Number of Applications	4 (maximum)	4
Timing/Retreatment Interval	10-21 days	10-11 days
Individual Application Rate	0.292 lb ai/A	0.30
Seasonal Application Rate	1.17 lb ai/A	1.2
Pre-harvest Interval	0 days	0 days
Maximum Residue	N/A	1.51 (lemons)
Restrictions	0-Day PHI; 14-day plantback interval (except crops listed on label).	N/A
Residue Data Source	N/A	BASF Residue Study: "Magnitude of BAS 500 02 F and BAS 510 02 F Residues in Citrus" Record Number 213564
Performing Laboratory	N/A	BASF Agro Research, Research Triangle Park, NC

Processed Food and Feed

No processing data were submitted with the field trial data on oranges, grapefruit, or lemons. However, the California DPR submission stated that mandarin oranges are not generally processed.

Meat, Milk, Poultry, and Eggs

Dried citrus pulp is a potential animal feed item associated with mandarin oranges. Dried citrus pulp could be a significant feed item for beef and dairy cattle, but not for swine and poultry. A maximum theoretical dietary burden (MTDB) was constructed for cattle as part of the original risk assessment for boscalid in 2003. Dried citrus pulp would not affect the MTDB, however, because other feed items with higher potential residues already account for 100% of the MTDB. As a result, the animal commodity tolerances currently in effect are adequate to cover the requested Section 18 use on tangerines.

Rotational Crop Restrictions

Rotational Crop restrictions follow the registered label use for Pristine Fungicide. Crops appearing on the label may be rotated at any time. All other crops may be rotated 14 days after the final application of boscalid.

Dietary Exposure Analysis

A chronic dietary exposure analysis was performed for boscalid (Memo, D316141, D. Dotson, 5/5/05). The chronic dietary analysis is a conservative assessment based on tolerance level residues and 100% crop treated assumptions for all commodities. Results of these analyses are summarized in Table 7.

Table 7. Summary of Dietary Exposure and Risk for Boscalid				
Population Subgroup	Acute Analysis	DEEM: Chronic Analysis		Cancer Analysis
		Dietary Exposure (mg/kg/day)	% cPAD	
General U.S. Population	Not Applicable: No Acute Dietary Endpoint	0.014631	6.7	Not Applicable: No cancer risk assessment is required
All Infants (< 1 year old)		0.035116	16	
Children 1-2 years old		0.056953	26	
Children 3-5 years old		0.039243	18	
Children 6-12 years old		0.019212	8.8	
Youth 13-19 years old		0.010487	4.8	
Adults 20-49 years old		0.010370	4.8	
Adults 50+ years old		0.010957	5.0	
Females 13-49 years old		0.010373	4.8	

Drinking Water Considerations

Drinking water monitoring data were not available for quantitative incorporation of drinking water residues into this risk assessment. EFED provided estimated drinking water concentrations (EDWCs) for the use of boscalid on tangerines. The estimated surface water concentration is 15 ppb and the estimated groundwater concentration is 0.5 ppb. In the previous water analysis performed by EFED (for the use of boscalid on soybeans, pome fruit, and hops), higher EDWCs were provided because the assessment was based on the plant with the highest application rate, turf. For this Section 18, the previous numbers will be used in order to be conservative and, therefore, protective of human health. The chronic surface water value based on the use on turf is 26 ppb and the groundwater value is 0.6 ppb.

HED has calculated drinking water levels of comparison (DWLOCs) for the most highly exposed population subgroups for the various aggregate exposure scenarios that are appropriate for boscalid. These DWLOCs are discussed in the aggregate risk section below.

Non-Dietary, Non-Occupational Exposure

The non-occupational/residential exposure/risk assessment is based on HED's first ORE assessment for boscalid (D290072, by S. Wang, M. Collantes, G. Bangs 6/18/03). The results of the assessment are summarized as follows:

Potential non-occupational exposure scenarios were identified for golfers and persons harvesting fruit at "U-pick" farms and orchards. Residues may be contacted from treated golf course turf or while picking strawberries, caneberries, and tree fruit. Based on its low vapor pressure and outdoor uses, no post-application inhalation exposures are anticipated for boscalid. Because "U-pick" is a "one-time" event (duration <1 day) and the HIARC found that the oral studies used to select endpoints were not appropriate to quantitate acute risk, "U-pick" exposure/risk was also not evaluated for non-inhalation scenarios. Only the golfing scenario, for which short-term exposure (1-30 days) is expected, is evaluated in this assessment.

The boscalid label specifies that this product is intended for golf course use only, and not for use on residential turfgrass or turfgrass being grown for sale or other commercial use such as sod production. Although the label does not indicate that the product is applied by licensed or commercial applicators, it is acknowledged that the homeowner will not be applying the product to golf courses. Therefore, a risk assessment for residential handler exposure is not required. Boscalid is not packaged or marketed for home orchard use and, therefore, that use is not assessed.

It has been determined that the potential exists for exposure to boscalid from entering areas previously treated with the fungicide. Based on the above discussion, there is only one potential non-occupational post-application scenario associated with boscalid for which risk needs to be assessed: adults and youths golfing (Table 8). Duration of exposure is anticipated to be short-term.

Table 8. Non-Occupational Post-application Exposure Scenario for Boscalid			
Scenario, Product, Formulation	Method of Application	Use Sites	Application Rate
BAS 510 02F Turf Fungicide, EPA Reg No. 7969-Pending	ground equipment only	golf course use only	0.5 lb ai/A

Turf Transferable Residue Data:

The Registrant, BASF Corporation, submitted a turf transferable residue study using boscalid in support of this registration action. The Health Canada Pest Management Regulatory Agency (PMRA) performed the primary review of the study and HED performed the secondary review. HED concurred with the DFR study reviews done by PMRA.

Assumptions:

- adult transfer coefficient is 500 cm²/hr (based on HED SOP 3.1)
- duration of exposure is estimated to be 4 hours (assuming chemical is used on all parts of a course (greens, tees, and fairways) and an adult plays 18 holes of golf)

As youths and adults have similar body surface area to weight ratios, their doses are expected to be similar. Therefore, a separate calculation for youths is not necessary.

Equations and Calculations:

$$PDR_o = TTR_o \times CF1 \times Tc \times ET \times \% DA$$

where

PDR _o	=	potential dose rate on day 0 (mg/day)
TTR _o	=	turf transferable residue on day 0 (ug/cm ²); note highest TTR used, which may have occurred on subsequent day after application
CF1	=	unit conversion factor to convert µg units in the DFR to mg for daily exposure (0.001 mg/µg)
Tc	=	transfer coefficient (500 cm ² /hr)
ET	=	exposure time (4 hr/day)
%DA	=	percent dermal absorption (15%)

The non-occupational dermal post-application exposure/risk were calculated by coupling turf specific TTR values with activity specific transfer coefficient (Tc) values from the HED Science Advisory Council For Exposure Policy Number 3.1: Agricultural Transfer Coefficients, August 2000. The high end transfer coefficients for each activity were used for this screening level assessment.

The TTR study provided two residue values, both from Pennsylvania. The highest turf average daily residue value (0.1313 µg/cm²) was collected from a sampling site when the turf was wet, which is assumed to have resulted in higher than normal transferable residues. The lower turf residue value (0.048 µg/cm²) was collected when the turf was dry and resulted in lower transferable residues. It should be noted that the Tc used to estimate dermal exposure to turf is based on samples collected on dry surfaces. However, golf courses are often automatically sprayed by built in sprinkler systems in the morning. Therefore, HED deemed it appropriate to assess dermal exposure in both dry/wet conditions. The TTR values were normalized (adjusted) to the maximum label application rate.

Table 9 provides a summary of dermal post-application exposure for golfing. The MOEs were all greater than the target MOE of 100 and, therefore, did not exceed HED's level of concern.

Table 9. Dermal Post-application Exposure for Adults and Youths								
Scenario & Product	DFR/TTR ¹ (µg/cm ²)	CF1 (mg/µg)	Tc (cm ² /hr)	ET (hr/day)	% DA	BW (kg)	Daily Dose ² (mg/kg/day)	Dermal MOE ³
Golfing								
BAS 510 02F Turf Fungicide	0.069 ^a	0.001	500	4	15	70	0.000295	74000
TTR Study MRID# 45405301	0.188 ^b						0.0008	27000

1a. The highest daily average Transferable Turf Residue for dry turf resulting from Pennsylvania TTR study data (Adjusted for difference in application rate from 0.35 to .5 lb ai/A max rate)

1b. The highest daily average Transferable Turf Residue for wet turf resulting from Pennsylvania TTR study data (Adjusted for difference in application rate from 0.35 to .5 lb ai/A max rate)

2. $DD \text{ (mg/kg/day)} = DFR \times CF1 \times Tc \times ET \times \%DA/BW$

3. $\text{Dermal MOE} = \text{NOAEL (21.8 mg/kg/day)} / \text{Daily Dose (mg/kg/day)}$

Spray drift is always a potential source of exposure to residents living in close proximity to spraying operations. This situation is particularly the case with aerial application. However, to a lesser extent, spray drift resulting from the ground application of boscalid could also be a potential source of exposure. The Agency has been working with the Spray Drift Task Force (a membership of U.S. pesticide registrants), EPA Regional Offices, State Lead Agencies for pesticide regulation, and other parties, to develop the best spray drift management practices. For aerial applications, the Agency is now requiring interim mitigation measures that must be placed on product labels/labeling. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, and is developing a policy on how to apply appropriately 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 pesticide application.

Aggregate Risk

Acute Risk

As there were no toxic effects attributable to a single dose of boscalid, an endpoint of concern was not identified to quantitate acute dietary risk. As a result, an acute aggregate risk assessment is not needed.

Short-Term Risk

The short-term aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and non-occupational uses (golf courses). Postapplication exposures from the proposed use on golf courses is considered short-term, and applies to adults and youths. Therefore, a short-term aggregate risk assessment was conducted. As all endpoints are from the same study, exposures from different routes can be aggregated. Table 10 summarizes the results. The MOE from food and non-occupational uses is 1400, and the calculated short-term DWLOC is 6100 ppb. Compared to EFED's surface and

ground water EDWCs, the DWLOC is considerably greater. Therefore, short-term aggregate risk does not exceed HED's level of concern.

The MOE and DWLOC are considered to be representative for youth because youths and adults possess similar body surface area to weight ratios, and because the dietary exposure for youth (13-19 years old) is less than that of the general U.S. population.

Table 10. Short-Term Aggregate Risk and DWLOC Calculations for the General U.S. Population (Inhalation/Oral/Dermal Endpoints and NOAELs the Same)

Popula- tion	Short-Term Scenario									
	NOAEL mg/kg/day	Target MOE	Max Exposure ² mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure ³ mg/kg/day	Aggregate MOE (food and residential) ⁴	Max Water Exposure ⁵ mg/kg/day	Ground Water EDWC ⁶ (ppb)	Surface Water EDWC ⁶ (ppb)	Short- Term DWLOC ⁷ (ppb)
U.S.	21.8	100	0.218	0.014631	0.0008	1400	0.2026	0.6	26	6,100

¹ The target MOE for dermal is 100.

² Maximum Exposure (mg/kg/day) = NOAEL/Target MOE

³ Residential Exposure = Dermal exposure from golf course only

⁴ Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]

⁵ Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)

⁶ The crop producing the highest level was used.

⁷ DWLOC(μg/L) = $\frac{\text{maximum water exposure (mg/kg/day)} \times \text{body weight (kg)}}{[\text{water consumption (L)} \times 10^{-3} \text{ mg/}\mu\text{g}]}$

⁸ Adult female body weight (60 kg) was used, which covers adult male risk. The dietary exposure for the U. S. population is higher than that of groups having residential (golf) exposure (i.e., adults, youth 13-19).

Intermediate-Term Risk

As no intermediate-term non-occupational exposures are anticipated, an intermediate-term aggregate risk assessment is not needed.

Chronic Risk

The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of boscalid (food and drinking water) and residential uses. As the exposure resulting from contact with turf grass (golf courses) is considered short-term, the chronic aggregate assessment includes food and drinking water only. DWLOCs were calculated for the population subgroups given in Table 7. They range from 1,600 to 7,300 ppb. The most highly exposed population subgroup is Children 1-2 years old, which has a DWLOC of 1,600 ppb. Adults 20-49 and Adults 50+ both have a DWLOC of 7,300 ppb. The DWLOCs for the general U.S. population, children 1-2, and females 13-19 are given in Table 11. EDWCs generated by EFED are less than HED's calculated chronic DWLOCs for the general U.S. population and all population subgroups. Therefore, the chronic aggregate risk associated with the use of boscalid does not exceed HED's level of concern.

Table 11. Chronic Drinking Water Levels of Comparison for Boscalid						
Population Subgroup	PAD, mg/kg bwt/day	Exposure, mg/kg bwt/day			Concentration, µg/L	
		Food	Non-Dietary	Max. Allowable Water ¹	Drinking Water Level of Comparison ²	EDWC ³
Chronic Exposure						
U.S. Population	0.218	0.014631	N/A	0.203369	7,100 ppb	26 ppb
Children 1-2 Years	0.218	0.056593	N/A	0.161407	1,600 ppb	26 ppb
Females 13-49	0.218	0.010373	N/A	0.207627	6,200 ppb	26 ppb
¹ Maximum Allowable Water Exposure = PAD - sum of all quantifiable exposures. ² Drinking Water Level of Comparison = Maximum Allowable Water Exposure × Body Weight (10 kg infants and children, 60 kg females, 70 kg all others) × 1000 µg/mg ÷ Consumption (1 L/day infants and children, 2 L/day all others). ³ EDWC (Estimated Drinking Water Concentration) is the chronic surface water value provided by EFED.						

Attachment 1: MRL Status Sheet for Boscalid

cc: D. Dotson, S. Wang

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro [1,1'-biphenyl]-2-yl)	Common Name: Boscalid	☒ Proposed tolerance ☐ Reevaluated tolerance ☐ Other	Date: 4/20/2005
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
☒ No Codex proposal step 6 or above ☐ No Codex proposal step 6 or above for the crops requested		Petition Number: 04CA21 DP Barcode: D309981 Other Identifier:	
Residue definition (step 8/CXL): Not applicable		Reviewer/Branch: Doug Dotson/RAB2	
		Residue definition: parent boscalid	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Tangerines	2.0
		Mandarin Oranges	2.0
		Oranges	2.0
		Lemons	2.0
		Grapefruit	2.0
Limits for Canada		Limits for Mexico	
☐ No Limits ☒ No Limits for the crops requested		☒ No Limits ☐ No Limits for the crops requested	
Multiple registered crops uses (12/23/04, but no MRLs). No citrus uses. Residue definition: ?		Residue definition: N/A	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
Notes/Special Instructions: S.Funk, 04/25/05.			

Rev. 1998