UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 08/MAR/2006

SUBJECT: Bentazon: Human Health Risk Assessment for Proposed Uses on Peaches. PC Code: 275200 and 103901, Petition No. 2E6501, DP Barcode: D322258.

Regulatory Action: Proposed Tolerance Petition
Risk Assessment Type: Single Chemical Aggregate

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The Technical Review Branch (TRB), ARIA Team, of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. RD of OPP has requested that TRB evaluate hazard and exposure data and conduct dietary, occupational, residential and aggregate exposure assessments, as needed, to estimate the risk to human health that will result from proposed use of bentazon on peaches.

A summary of the findings and an assessment of human risk resulting from the proposed use of bentazon (Basagran‘ Herbicide, EPA Reg. No. 7969-45) are provided in this document. The risk assessment and the residue chemistry data review were provided by Debra Rate (TRB), the dietary risk assessment was provided by Debra Rate (TRB), the occupational/residential exposure assessment by Mark Dow (RAB1), and the drinking water assessment by Norman Birch of the Environmental Fate and Effects Division (EFED).

NOTE: HED recently completed a Section 3 risk assessment for the use of bentazon on flax and clover grown for seed. (DP Barcode: D273508, G. Kramer, 06/14/2001). This document contains only those aspects of the risk assessment which are affected by the addition of this new use of bentazon on peach.

Recommendation for Tolerances and Registration

TRB concludes there are no residue chemistry or toxicology data requirements that would preclude the establishment of a conditional registration for the use of bentazon on peach and the following permanent tolerances for combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in/on:

peach	--	0.05 ppm

However, Dietary Risk Assessment shows that acceptable chronic exposure levels are exceeded with current and proposed uses of bentazon.

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1.0 EXECUTIVE SUMMARY

Basagran® is a post emergence herbicide used for control of several broadleaf weeds and sedges. It is applied by ground or air. Bentazon is a list A active ingredient. A Reregistration Eligibility Decision Document (RED) chapter for bentazon was completed by HED in 1994 (DP Barcodes: D188712 and D196299, P. Deschamp, 2/7/94 and 8/15/94). In addition to being registered for use on terrestrial food and feed crops, Basagran® is also registered for use on turf and ornamentals.

Hazard Assessment

The acute toxicity data for bentazon show that this chemical is not acutely toxic by the oral, inhalation, or dermal routes of exposure (Toxicity Categories III and IV). It is moderately irritating to the eye (Toxicity Category II) and slightly irritating to the skin (Toxicity Category IV). Bentazon is also a dermal sensitizer. In subchronic studies in rats and dogs and in chronic studies in rats, mice, and dogs, the most toxicologically significant effects were changes in hematology/coagulation parameters following bentazon administration. Chronic studies in rats, mice and dogs support the anticoagulant effects seen in the subchronic studies. Chronic dietary administration of bentazon causes overt anticoagulant effects [increased prothrombin times (PT) and/or partial thromboplastin times (PTT)] at 35-50 mg/kg/day in mice, rats, and dogs. No systemic or dermal toxicity was seen at the limit dose of 1000 mg/kg/day in a 21-day dermal toxicity study in rabbits. There was no evidence of carcinogenic potential in either the rat or mouse study. Both the rat developmental and reproductive toxicity studies indicate increased susceptibility from *in utero* and post natal exposure to bentazon. The available developmental toxicity data in rabbits did not provide an indication of increased susceptibility from *in utero* exposure to bentazon. There is no concern for mutagenicity.

Dose Response Assessment

On June 10, 1999 the HED Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology data base of bentazon and re-assessed the Reference Dose (RfD) established in 1991, as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to bentazon as required by the Food Quality Protection Act (FQPA) of 1996. The HED FQPA Safety Factor Committee (SFC) met on July 26, 1999 to evaluate the hazard and exposure data for bentazon and recommended that the FQPA safety factor (SF) be retained at 10x in assessing the risk posed by this chemical because there was evidence of increased susceptibility in the developmental toxicity study in rats and in the two-generation reproduction toxicity study in rats. The 10x FQPA SF is applicable to females 13-50 years old for acute dietary and residential exposure assessments and to all population subgroups for chronic dietary and residential exposure assessments. The acute and chronic Population Adjusted Doses (aPAD and cPAD, respectively) are modifications of the acute and chronic RfDs to include the FQPA SF. The acute or chronic PAD is equal to the acute or chronic RfD divided by the FQPA SF.

An acute reference dose (aRfD) of 1 mg/kg/day was established for the subpopulation group, females 13-50 years old only, from a developmental toxicity study in the rat. The no-observed-adverse-effect level (NOAEL) of 100 mg/kg/day was based on an increase in postimplantation loss, skeletal variations, and reduced weight of fetuses seen at the lowest-observed-adverse-effect level (LOAEL) of 250 mg/kg/day (highest dose tested). These effects are presumed to occur after a single exposure in utero and, therefore, are considered to be appropriate for this risk assessment. The FQPA SFC recommended that the 10x FQPA SF be applied to females 13-50 years old, therefore, the aPAD is 0.1 mg/kg/day for this population subgroup. An acute dose and endpoint were not selected for the general U.S. population (including infants and children) because there were no effects observed in oral toxicology studies, including maternal toxicity in the developmental toxicity studies in rats and rabbits, that are attributable to a single exposure (dose).

The cRfD of 0.03 mg/kg/day was determined on the basis of a one-year feeding study in dogs. The NOAEL of 3.2 mg/kg/day was based on a dose-dependent presence of feces with red areas in dogs seen at the LOAEL of 13.1 mg/kg/day. Feces with red areas were also present at the high dose (52.3 mg/kg/day). This RfD was originally established in the RfD document dated February 12, 1991 and re-confirmed by the HED/Peer Review Committee on July 1, 1993. The FQPA SF of 10x is applicable for chronic dietary risk assessment. Thus, the cPAD is 0.003 mg/kg/day.

Bentazon has been classified as a Group ■E• chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in two adequate studies (rats and mice) (TXR 010787, J. Rowe, 1/14/92).

A short-term dermal dose/endpoint was not identified since no dermal or systemic toxicity was seen at the limit dose of 1000 mg/kg/day in a 21-day dermal toxicity study in rabbits. An intermediate-term dermal endpoint was chosen from a one-year feeding study in dogs. The HIARC selected a NOAEL of 13.1 mg/kg/day based on the presence of feces with red areas seen in dogs at weeks 4, 6, and 12 at a LOAEL of 52.3 mg/kg/day. A long-term dermal endpoint was chosen from a one-year feeding study in dogs. The HIARC selected a NOAEL of 3.2 mg/kg/day based on a dose-dependent presence of feces with red areas in dogs at the LOAEL of 13.1 mg/kg/day (400 ppm). The HIARC determined that since oral NOAELs were selected, a dermal absorption (DA) factor of 2%, obtained from a dermal penetration study, should be used for risk assessment.

No appropriate inhalation studies were available for endpoint selection; therefore, HIARC selected oral NOAELs for inhalation exposure risk assessment. For margin of exposure (MOE) calculations, the short-term inhalation exposure NOAEL is 100 mg/kg/day (from a developmental toxicity study in rats, therefore, use 100% inhalation absorption). Dermal exposure **can not** be combined with inhalation, since a dose/endpoint (hazard) was not identified for short-term dermal exposure risk assessment. The intermediate- and long-term inhalation exposure NOAELs are 13.1 mg/kg/day and 3.2 mg/kg/day, respectively, from a chronic dog study. For intermediate- and long-term inhalation exposure risk assessments, the dermal and inhalation exposures **can** be combined (using 100% absorption for inhalation and 2% absorption for dermal) since the doses selected are oral equivalent doses and the same toxic effect was observed (feces with red areas).

Occupational Exposure Estimates

Based on the proposed use patterns, commercial and private (i.e., grower operators) pesticide handlers are typically expected to have short-term exposures (i.e., 1-30 days). However, the HED Science Advisory Council for Exposure (ExpoSac) asserts that there is a possibility that commercial handlers might be exposed to intermediate-term exposures (1 - 6 months). Therefore, estimated risks are presented for short- and intermediate-term exposures. The HIARC identified a short-term dermal toxicological endpoint, a short-term inhalation toxicological endpoint, and an intermediate-term dermal endpoint. Based upon the proposed label directions, exposure estimates are presented for a mixer/loader using ■open pour liquids• and for an open cab, ground boom applicator. These activities are considered the most conservative (i.e., most highly exposed). The proposed labels indicate that handlers must wear

long sleeved shirts, long pants, shoes plus socks and waterproof gloves. Under these conditions all MOEs are above 100 and are therefore below HED=s level of concern.

Residue Chemistry

Crop field trials of bentazon on peaches indicated that the residue levels would not exceed 0.05 ppm (D315268, D. Rate, 06/OCT/2005). TRB recommended that the tolerance be set at the requested tolerance of 0.05 ppm for bentazon on peaches. Residue analytical methods for measuring bentazon residues on peaches are adequate for enforcement. Confined accumulation in rotational crops studies were not necessary since peaches are an orchard crop and are not rotated.

Dietary Exposure Estimates

Acute and chronic dietary exposure analyses were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, ver 2.03), which incorporates consumption data from the USDA 1994-96, 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The acute analysis was based on conservative assumptions (tolerance level residues, 100% crop treated (%CT), and DEEM-ver.7.81 default concentration factors were used for all commodities). For the chronic analysis, anticipated residues (ARs) were calculated for succulent peas. Percent CT information for several commodities was obtained from the Biological Economic and Analysis Division (BEAD). For all other commodities 100% CT was assumed. DEEM-FCID default concentration factors were used for all commodities. The residues from drinking water were included in the Dietary Exposure analysis. The acute dietary food exposure estimates were less than TRB=s level of concern (<100% aPAD) for the general US population and all population subgroups (D322256, D. Rate, 09/JAN/2006). However, the chronic dietary food exposure estimates exceeded TRB's level of concern (>100% cPAD) for infants (<1 year) and non-nursing infant population subgroups (D322256, D. Rate, 09/JAN/2006). Specifically, the acute dietary risk estimate occupied □5% of the aPAD for females 13-49 years old, while the chronic dietary risk estimates occupied #135% of the cPAD for all population subgroups.

Drinking Water

The Environmental Fate and Effects Division (EFED) provided a drinking water assessment of bentazon alone and bentazon plus all degradates (AIBA (animal commodities), 6-hydroxy bentazon (plant commodities), and 8-hydroxy bentazon (plant commodities)). The more conservative estimated environmental concentration (EEC) for bentazon + all degradates to be used for the acute and chronic scenarios is based on surface water modeling. The EEC for surface water (from PRZM-EXAMS modeling) is 77.7 ppb for the peak (acute) and 49.9 ppb for the 36-year annual mean (chronic).

Exposure Scenarios and Risk Conclusions

For the proposed uses on peaches, human health risk assessments have been conducted for the following exposure scenarios: aggregate acute exposure (food and water) and aggregate chronic exposure (food and water); short-term exposure (short-term inhalation exposures from residential uses); short-term aggregate exposure (background chronic dietary exposure (food + drinking

water) and short-term inhalation exposures from residential uses); intermediate-term exposure (intermediate-term dermal exposures from residential uses); intermediate-term aggregate exposure (background chronic dietary exposure (food + drinking water) and intermediate-term dermal exposures from residential uses); and short- and intermediate-term occupational exposure. Other scenarios were not evaluated since bentazon has not been classified as a carcinogen and long-term occupational and residential exposure is not expected. E**xposure estimates do not exceed TRB's level of concern, except for aggregate chronic.**

Recommendation for Tolerances and Registration

TRB concludes there are no residue chemistry or toxicology data requirements that would preclude the establishment of a conditional registration for the use of bentazon on peaches and the following permanent tolerances for combined residues of the herbicide bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in/on:

Peach	--	0.05 ppm

However, Dietary Risk Assessment shows that acceptable chronic exposure levels are exceeded with current and proposed uses of bentazon.

2.0 HAZARD CHARACTERIZATION

A complete hazard characterization is presented in the Section 3 risk assessment for the use of bentazon on succulent peas (DP Barcode: D225923, J. Kidwell, 11/15/99). For purposes of clarity, the dose response assessment is summarized below.

2.1 Dose Response Assessment

On June 10, 1999 the HED HIARC evaluated the toxicology database of bentazon and re-assessed the RfD established in 1991, as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to bentazon as required by FQPA (HED DOC. NO. 013697, B. Tarplee, 6/25/99).

FQPA Recommendation

The HED FQPA SFC met on July 26, 1999 to evaluate the hazard and exposure data for bentazon and recommended that the FQPA SF (as required by FQPA of August 3, 1996) be retained at 10x in assessing the risk posed by bentazon. This decision is based on 1) evidence of increased susceptibility following *in utero* exposure to bentazon in the prenatal developmental toxicity study in rats in the absence of maternal toxicity, and 2) quantitative evidence of increased susceptibility following pre-/postnatal exposure to bentazon in the 2-generation reproduction study in rats (HED DOC. NO. 013697, B. Tarplee, 6/25/99).

The FQPA SF for bentazon is applicable to females 13-50 years old only for acute dietary and residential exposure assessments since increased susceptibility was demonstrated in both the

developmental study in rats which is designed to evaluate chemical effects on the mother and fetus from the time of implantation of the fertilized egg into the wall of the uterus through birth.

The SF is also applicable to all population subgroups for chronic dietary and residential exposure assessments since increased susceptibility was demonstrated in the 2-generation reproduction study.

The aPAD and cPAD are modifications of the acute and chronic RfDs to accommodate the FQPA SF. The PAD is equal to the acute or chronic RfD divided by the FQPA SF. Since the HED FQPA SFC determined to retain the 10x SF, the RfD has been adjusted to reflect the PAD. Therefore, the aPAD for females 13-50 years old is 0.1 mg/kg/day (1 mg/kg/day) 10 = 0.1 mg/kg/day), and the cPAD for the U.S. general population and all population subgroups is 0.003 (0.03 mg/kg/day) 10 = 0.003 mg/kg/day) for chronic dietary exposure.

Cancer

Bentazon has been classified as a Group ■E• chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in rats and mice (TXR 010787, J. Rowe, 1/14/92). Therefore, a cancer dietary exposure and risk assessment is not required.

Short-, Intermediate-, and Long-term Inhalation Endpoints

No acceptable inhalation studies were available for evaluation. Therefore, the HIARC selected oral NOAELs for inhalation risk assessment.

For short-term inhalation exposure risk assessment, the inhalation exposure component (i.e., Φg a.i./L/day) using 100% absorption rate (default value), application rate, and number of acres treated should be converted to an equivalent oral dose (mg/kg/day). This dose then should be compared to the oral developmental toxicity NOAEL of 100 mg/kg/day (from the developmental toxicity study in rats) to calculate the MOE. Dermal exposure can NOT be combined with inhalation, since a dose/endpoint (hazard) was not identified for short-term dermal exposure risk assessment.

For intermediate- and long-term risk assessment, the dermal and inhalation exposures can be combined since the endpoints were based on the same studies (same NOAELs and effects). The risk assessment should follow the route-to-route extrapolation as below:

Step I The inhalation exposure component (i.e. Φg a.i./L/day) using 100% absorption rate (default value) and application rate should be converted to an equivalent oral dose (mg/kg/day).

Step II The dermal exposure component (i.e. Φg a.i./L/day) using 2% absorption rate and application rate should be converted to an equivalent oral dose (mg/kg/day).

Step III The equivalent oral doses (Step I and II) should be combined and then compared to the oral NOAELs for the appropriate exposure periods to calculate the MOEs. The NOAELs (from a chronic dog toxicity study) are as follows:

For Intermediate Term: NOAEL = 13.1 mg/kg/day
For Long-Term: NOAEL = 3.2 mg/kg/day

Although long-term dermal and inhalation endpoints were selected, the current use pattern does not indicate a potential for long-term dermal or inhalation exposure. Long-term dermal and inhalation risk assessments were not conducted for this action.

MOEs

The level of concern for both dermal and inhalation occupational risk assessments is an MOE of 100. The level of concern for both dermal and inhalation residential exposure risk assessments is an MOE of 1000 (includes 10x FQPA SF).

The doses and toxicological endpoints selected for various exposure scenarios are summarized in Table 1.

Table 1. Summary of Toxicological Endpoints for Use in Human Risk Assessment

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary (Females 13-50 years old)	Developmental NOAEL = 100 UF = 100 FQPA SF = 10	Increased postimplantation loss, skeletal variations, and reduced weight of fetuses at a LOAEL of 250 mg/kg/day.	Developmental Toxicity- Rat
	Acute RfD = 1 mg/kg **Acute PAD** = 0.1 mg/kg		
Acute Dietary (General Population)	None	A dose and ▪non-developmental• endpoint attributable to a single exposure were not identified in oral toxicity studies.	None
	Risk Assessment is NOT required.		
Chronic Dietary	NOAEL = 3.2 UF = 100 FQPA SF = 10	A dose-dependent presence of feces with red areas in dogs at 13.1 mg/kg/day (LOAEL) and 52.3 mg/kg/day (HDT), and slight to severe anemia at the high dose.	One-Year Feeding Study- Dog
	Chronic RfD = 0.03 mg/kg/day **Chronic PAD** = 0.003 mg/kg/day		
Short-Term	No systemic toxicity was seen at the Limit-Dose in a 21-day dermal toxicity study in rabbits.		

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
(Dermal)	Therefore, this risk assessment is NOT required.		
Intermediate-Term (Dermal)[a]	Oral NOAEL = 13.1 MOE = 100 (Occupational) MOE = 1000 (Residential)	The presence of feces with red areas seen in dogs at weeks 4, 6, and 12 at a LOAEL of 52.3 mg/kg/day.	One-Year Feeding Study-Dog
Long-Term (Dermal)[a, d]	Oral NOAEL = 3.2 MOE = 100 (Occupational) MOE = 1000 (Residential)	A dose-dependent presence of feces with red areas in dogs at a LOAEL of 13.1 mg/kg/day (seen at week 33) and 52.3 mg/kg/day (HDT), and slight to severe anemia at the high dose.	One-Year Feeding Study-Dog
Short Term (Inhalation)[b]	Oral Developmental NOAEL= 100 MOE = 100 (Occupational) MOE = 1000 (Residential)	Increased postimplantation loss, skeletal variations, and reduced weight of fetuses at a LOAEL of 250 mg/kg/day.	Developmental Toxicity- Rat
Intermediate Term (Inhalation)[c]	Oral NOAEL = 13.1 MOE = 100 (Occupational) MOE = 1000 (Residential)	The presence of feces with red areas seen in dogs at weeks 4, 6, and 12 at a LOAEL of 52.3 mg/kg/day.	One-Year Feeding Study-Dog
Long Term (Inhalation)[c,d]	Oral NOAEL=3.2 MOE = 100 (Occupational) MOE = 1000 (Residential)	A dose-dependent presence of feces with red areas in dogs at a LOAEL of 13.1 mg/kg/day (seen at week 33) and 52.3 mg/kg/day (HDT), and slight to severe anemia at the high dose.	One Year Feeding Study-Dog

[a] A dermal absorption factor of 2% should be used for route-to-route extrapolation.
[b] An inhalation absorption factor of 100% should be used for route-to-route extrapolation for short-term inhalation risk assessment.
[c] An inhalation absorption factor of 100% and a dermal absorption factor of 2% should be used for route-to-route extrapolation for intermediate- and long-term risk assessments.
[d] Although long-term dermal and inhalation endpoints were selected, the current use pattern does not indicate a concern for long-term dermal or inhalation exposure potential. Long-term dermal and inhalation risk assessments were not conducted.

3.0 EXPOSURE ASSESSMENT

3.1 Summary of Proposed Uses

Peach: Basagran® will be applied when weeds first emerge and peaches are in the early stages of

growth. Application rates are dependent upon weed type, with a maximum application rate of 1 qt formulation per acre per application. Not more than 2 applications per season are permitted, for a seasonal maximum of 2 qt/A (2 lb ai/A/season). A preharvest interval (PHI) of 15 days is specified. The label also specifies use of ground equipment using a minimum of 10 gallons water/A, with up to 5% (v/v) oil concentrate added, if desired. Application through irrigation systems is prohibited.

3.2 DIETARY EXPOSURE/RISK PATHWAY

3.2.1 RESIDUE PROFILE

Interregional Research Project No. 4 (IR-4) has submitted a petition (PP# 6E04703) on behalf of the Agricultural Experiment Stations of WA and OR proposing the following permanent tolerances for the combined residues of the herbicide bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in/on:

Peaches -- 0.05 ppm

Permanent tolerances already exist under 40 CFR 180.355(a) for combined residues of bentazon and its 6- and 8-hydroxy metabolites in/on a variety of crops, including corn, rice, soybeans and sorghum. Livestock commodity tolerances are established for bentazon and its metabolite AIBA at 0.05 ppm in 40 CFR 180.355(b).

Conclusions: The directions for use of bentazon on peaches have been adequately delineated on the Basagran‘ label.

Nature of the Residue

Plants: The qualitative nature of the residue in plants is considered to be adequately understood (See 2/7/94 RED Chapter). Radiolabeled studies conducted at rates of up to 2.5 lb ai/A on beans, corn, soybeans, rice and wheat indicate that bentazon is readily absorbed from foliage, roots and seeds, and translocates in some plant types. Bentazon is rapidly metabolized, conjugated and incorporated into natural plant constituents. Metabolism involves the hydroxylation of bentazon at the 6- and 8-position. The terminal residues of regulatory concern are bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon.

Livestock: The qualitative nature of the residue in livestock is considered to be adequately understood (See 2/7/94 RED Chapter). When dairy cattle were orally dosed with radiolabeled bentazon at levels of up to 20 ppm for 28 days, analysis showed that it was absorbed and rapidly eliminated in the urine. Bentazon and its metabolite AIBA are the regulated terminal residues in tissues and milk. Studies involving laying hens dosed with radiolabeled bentazon at 100 ppm in the diet for 5 days demonstrated that limited accumulation and metabolism occurs. Greater than 80% of the total radioactive residue (TRR) in tissue and eggs was identified as unchanged bentazon. The highest radioactive residue levels were found in the liver, and 16% of the TRR in liver consisted of the N-glucuronide conjugate of bentazon. Bentazon and AIBA are the

regulated terminal residues in poultry commodities.

Residue Analytical Methods

Plants: Adequate enforcement methods are available for the determination of residues of bentazon and its 6- and 8-hydroxy metabolites in/on plant commodities. The Pesticide Analytical Method Volume II (PAM II) lists Method II, a gas liquid chromatography (GLC) method with flame photometric detection for the determination of bentazon and its hydroxy metabolites in/on corn, rice, and soybeans; the limit of detection (LOD) for each compound is 0.05 ppm. Method III, modified from Method II, is available for the determination of bentazon and its hydroxy metabolites in/on peanuts and seed and pod vegetables with a LOD of 0.05 ppm for each compound. These methods are adequate to enforce the tolerances associated with this petition.

Residues of bentazon and its regulated hydroxy metabolites were determined in the field trials using a slightly modified version of BASF Method 19A which was previously reviewed by HED (PP#3F4270, S. Willett, 10/24/94). The methodology involves extraction with methanol, hydrolysis to release conjugated metabolites, and derivatization with diazomethane. After clean-up using a silica column, residues are quantified using gas chromatography, equipped with a TSD. To confirm the efficiency of the methodology, control samples of peach RACs were fortified with bentazon, 6-OH-bentazon and 8-OH bentazon at levels of 0.05-5.0 ppm.

Livestock: Adequate enforcement methods are available in PAM II for the determination of residues of bentazon and AIBA in livestock commodities. The methods involve quantification by gas chromatography with flame photometric or nitrogen-specific Coulson conductivity detectors. Limits of quantitation (LOQ) range from 0.02 ppm in milk, to 0.05 ppm for most other commodities.

Multiresidue Method (MRM)

Bentazon and its regulated metabolites have not been tested using the FDA MRM protocols (CBRS# 12748, P. Deschamp, 8/15/94). TRB is willing to recommend in favor of a conditional registration while this deficiency is being resolved.

Crop Field Trials

Peach: Field trials were conducted in Regions 1 (NY, 1 trial), 2 (NJ, 1 trial; NC, 2 trials; TN, 1 trial), 5 (MI, 1 trial), 10 (CA, 3 trials) during the 1999 growing season. Experimental plots of peaches were treated with two applications of Basagran® at a rate of 1.0 lb ai/A/app, at intervals of 12 to 16 days (no adjuvant added). Samples of marketable peaches were harvested at normal maturity, resulting in a PHI range of 9 to 15 days. The residue levels in peach samples were <0.05 ppm of bentazon and <0.05 ppm of the metabolite equivalents (D315268, D. Rate, 10/06/2005). Based on the data submitted, residue levels are not expected to exceed the proposed tolerance of 0.05 ppm on peaches.

Processed Food/Feed

Peach: As there are no processed commodities associated with peaches, as per label uses, processing studies not are required to support the subject petition.

Meat, Milk, Poultry, Eggs

Tolerances for Meat, Milk, Poultry, and Eggs are not germane to this submission, since there are no peach feed items.

Confined Accumulation in Rotational Crops

Confined Accumulation in Rotational Crops studies are not germane to this submission, since peaches are an orchard crop and are not rotated.

International Harmonization of Tolerances

There are no Canadian, Mexican or Codex MRLs for bentazon on peaches.

3.2.2 Dietary Exposure Analysis

TRB conducts dietary (food only) risk assessments using DEEM-FCID, which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996, 1998. For acute dietary risk assessments, one-day consumption data are summed and a food consumption distribution is calculated for each population subgroup of interest. The consumption distribution can be multiplied by a residue point estimate for a deterministic exposure/risk assessment, or be used with a residue distribution in a probabilistic type risk assessment. Acute exposure estimates are expressed in mg/kg bw/day and as a percent of the aPAD. For chronic risk assessments, residue estimates for foods or food-forms of interest are multiplied by the average consumption estimate of each food/food-form of each population subgroup. Chronic exposure estimates are expressed in mg/kg bw/day and as a percent of the cPAD.

TRB notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups which may not be sufficiently represented in the consumption surveys, (e.g., nursing and non-nursing infants). However, risk estimates for these subpopulations are included in representative populations having sufficient numbers of survey respondents (e.g., all infants). The population subgroups listed in Tables 2 and 3 are subgroups having a sufficient number of respondents in the USDA 1994-1996, 1998 CSFII food consumption survey to be considered statistically reliable. It should be noted that direct and indirect sources of water at 77.7 ppm for acute and 49.9 ppm for chronic were included in the Dietary Exposure analysis (see Section 3.3 below).

3.2.2.1 Acute Dietary Exposure Analysis

For the acute analysis, tolerance level residues were used and 100% CT was assumed for all commodities. DEEM-FCID default processing factors were used for all commodities. Dietary exposures and associated acute risk for the females 13-49 years old are shown in Table 2.

Table 2. Summary of Results of Acute DEEM-FCID Analysis for Bentazon at 95th Percentile.

Subgroup	Exposure (mg/kg/day)	% aPAD
Females (13-49) years old)	0.005140	5

The acute exposure estimates for females 13-49 years old accounted for <1% of the aPAD at the 95th percentile. For acute dietary risk estimates, TRB's level of concern is >100% aPAD. The results of the acute analysis indicate that the acute dietary risk estimates for females 13-49 years old (at the 95th percentile) associated with the existing and proposed uses of bentazon do not exceed TRB's level of concern.

3.2.2.2 Chronic Dietary Exposure Analysis

For chronic risk assessments, an AR was calculated for succulent peas using average residue values (1.08 ppm) from the submitted crop field trials (DP Barcode: D225510, G. Kramer, 4/2/96). Percent CT information for several commodities was obtained from Steve Nako of the BEAD (Personal communication between S. Nako and J. Kidwell, 10/6/99). For all other commodities 100% CT was assumed. DEEM-FCID default processing factors were used for all commodities.

Chronic dietary exposure estimates for the U.S. population and other population subgroups (i.e., children, infants, females, and males) are presented in Table 3.

Table 3. Summary of Results from Chronic DEEM-FCID Analysis of Bentazon.

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. Population (Total)	0.001378	46
All infants (<1 year)	0.004042	135
Children 1-2 years	0.002787	93
Children 3-5 years	0.002319	77
Children 6-12 years	0.001532	51
Youth 13-19 years	0.001039	35
Adults 20-49 years	0.001207	40
Adults 50+ years	0.001252	42
Females 13-49 years	0.001190	40

The chronic exposure estimates for the general U.S. population and most population subgroups accounted for <100% of the cPAD, however, all infants (<1 year) were the most highly exposed population subgroup at 135% of the cPAD. For chronic dietary risk estimates, TRB's level of concern is >100% cPAD. The results of the chronic analysis indicate that the chronic dietary risk estimates for the existing and proposed uses of bentazon **exceed** TRB's level of concern for commodity contribution.

Table 4 shows the commodity contribution for water (direct and indirect sources) for all infants (<1yr) exceeded TRB's level of concern. A more complete listing of commodity contribution is listed in Attachment 6.

Table 4. Summary of Commodity Contribution of Water (direct and indirect sources) to Bentazon Dietary Risk.

Subgroups	Exposure (mg/kg/day)	% cPAD
All infants (<1 year)	0.0034485	115

3.2.2.2 Cancer Exposure Analysis

Bentazon has been classified as a Group ■E• chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in rats and mice (TXR 010787, J. Rowe, 1/14/92). Therefore, a cancer dietary exposure and risk assessment is not required.

3.3 WATER EXPOSURE/RISK PATHWAY

EFED provided a drinking water assessment for bentazon (DP Barcode: D323158, N. Birchfield, 06/JAN/2006). Degradation products of bentazon in the tolerance expression are 8-hydroxy bentazon (plants), 6-hydroxy bentazon (plants), and AIBA (animals).

3.3.1 Ground Water

EECs

SCI-GROW modeling indicates that bentazon residue concentrations in groundwater used as drinking water are not likely to exceed 5.67 ppb. Available groundwater monitoring data contain higher concentrations (e.g. 11.5 ppb) than the model result. Since the surface water-derived estimates indicate a higher concentration than the SCI-GROW screening model, TRB has chosen to use the conservative 77.7 ppb as the representative national Tier 1 water concentration for bentazon.

3.3.2 Surface Water

EECs

Preliminary analyses of tier 1 screening-level drinking water exposure estimates suggested that chronic exposures to surface-derived drinking water could exceed acceptable exposure values. As a result, a second tier modeling of high-end drinking water concentrations using the PRIZM and EXAMS models were conducted. Surface water estimates are based on results from the PRZM/EXAMS model and a simple, conservative rice paddy model (DP Barcode: D323158, N. Birchfield, 01/06/06).

Specific values entered into the PRZM/EXAMS model can be found in D323158 [(Table 3) (N. Birchfield, 01/06/06)]. The maximum application rate used in this model was 1.0 lb/ A which concurred with the usage on peaches and major use crops. These terrestrial crops included soybeans, peanuts, corn, mint, dry beans, sweet corn, green peas, green beans and sorghum. The highest acute peak concentration for bentazon + all degradates was 77.7 ppb (Kansas sorghum), and the highest chronic peak concentration was 49.9 ppb (Pennsylvania corn).

Tier II PRZM-EXAMS modeling indicates that cumulative bentazon residue (bentazon + all degradates) concentrations in surface water to be used as screening concentrations for bentazon are 77.7 ppb for the 1 in 10 year peak (acute) and 49.9 ppb for the 36 year annual mean (chronic). Since less than 5% of rice is treated with bentazon, it was decided that the water numbers referring to bentazon + all degradate on terrestrial (land/soil) crops would be used in the subsequent dietary analyses (both acute and chronic) (DP Barcode: D323158, N. Birchfield, 01/06/06).

Table 5. Screening-level Drinking Water Concentrations[1]

Chemical(s)	Use Type	Peak - Acute (mg/L)	Annual Average - Chronic (mg/L)
Bentazon	terrestrial crop	66.5	29.2
Bentazon plus all degradates	terrestrial crop	77.7	49.9
Bentazon plus all degradates	rice	1,600	1,600

[1](DP Barcode: D323158, N. Birchfield, 01/06/06)

3.4 RESIDENTIAL EXPOSURE/RISK PATHWAY

A detailed residential exposure assessment is presented in the Section 3 risk assessment for the use of bentazon on succulent peas (DP Barcode: D255923, J. Kidwell, 11/15/99). The conclusions of this assessment hold true for use on peach and thus are summarized below.

Because bentazon is registered for consumer use on turf and ornamentals, there is potential for residential exposure to adult applicators and adults and children entering recreational and residential areas treated with bentazon. The handler exposure is expected to be short-term while the post-application exposure is expected for both the short- and intermediate-term. However, since there is no short-term dermal endpoint, the residential post-application exposure cannot be aggregated with the handler exposure. Short-term, non-dietary ingestion exposure for toddlers is not assessed since HIARC determined that there is no acute dietary or oral endpoint applicable to infants and children (endpoint was applicable to women of child-bearing age). However, intermediate-term, non-dietary ingestion exposure to toddlers playing on treated turf is possible and was assessed using the intermediate-term endpoint identified from the one-year dog feeding

study. Intermediate-term exposure is not expected for the ornamental use. The level of concern for residential exposures to bentazon is for MOEs less than 1000.

There are no chemical-specific or site-specific data available to determine the potential risks associated with residential exposures from handling bentazon. Therefore, the exposure estimates are based on assumptions and generic data as specified by the December 18, 1997 Draft HED SOPs for Residential Exposure Assessments. Since bentazon is applied no more than twice per year, only short-term exposure is expected for the residential handler. Since HIARC did not identify a dermal endpoint of concern for the short-term duration, only inhalation exposure estimates are relevant. Assuming that a homeowner treats his lawn and ornamental plants on the same day, the aggregate inhalation short-term MOE is 5.0E+05 for the residential handler. This estimate indicates that the potential handler risks from residential uses of bentazon do not exceed HED=s level of concern.

EFED environmental fate data indicate that bentazon is moderately resistant to degradation ($t_{1/2}$ = 24-65 days). Due to the length of time bentazon is expected to remain in the environment, both short- and intermediate-term residential post-application exposures are expected. For toddlers playing on treated turf, the oral intermediate-term endpoint was used to assess toddler incidental ingestion exposures. Based on the residential use pattern, no long-term post-application residential exposure is expected. Short-term, non-dietary oral exposures to the toddler were not assessed since the subgroup of concern was identified as females 13-50 years old. This endpoint is not applicable to the infant and children population subgroups. No chemical specific data are available to address postapplication exposure to persons reentering residential/recreational areas treated with bentazon. Intermediate-term, post-application exposure is not expected from the ornamental use of bentazon.

The dermal post-application exposure from the turfgrass use for the adult results in an MOE of 9.1E+03. The MOEs for post-application exposures for the toddler are calculated as 6.4E+03 and 3.5E+03 for dermal and hand-to-mouth exposures, respectively. The aggregate intermediate MOE for post-application residential exposure to toddlers is 2.2E+03. Therefore, all residential post-application exposure estimates are well below HED=s level of concern. Since these estimates were calculated using screening-level assumptions, HED believes that the actual risks will be lower. For the intermediate-term, typical lawn maintenance practices such as mowing and watering are expected to expedite the dissipation of bentazon on turfgrass. Therefore, with less residue available, potential incidental hand-to-mouth exposures are expected to be substantially lower.

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 groundboom application methods. 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.

4.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

Aggregate exposure risk assessments were performed for the following: acute aggregate exposure (food + drinking water), short-term aggregate exposure (background chronic dietary exposure (food + drinking water) and short-term inhalation exposures from residential uses), intermediate-term aggregate exposure (background chronic dietary exposure (food + drinking water) and intermediate-term dermal exposures from residential uses) and chronic aggregate exposure (food + drinking water). A cancer aggregate risk assessment was not performed because bentazon has been classified as a Group ■E• chemical (TXR 010787, J. Rowe, 1/14/92).

4.1 Acute Aggregate Risk (food + drinking water)

The acute dietary exposure analysis assumed tolerance level residues, DEEM-FCID default processing factors, and 100% CT for all proposed commodities (Tier 1). Since the dietary exposure analysis already includes water exposure, no further calculations are required. The results of the acute analysis indicate that the acute dietary (food + drinking water) risk estimates for females 13-50 years old (at the 95th percentile) associated with the existing and proposed uses of bentazon do not exceed HED•s level of concern. **Thus, acute aggregate risk estimates are below TRB's level of concern.**

4.2 Chronic Aggregate Risk (food + drinking water)

For the chronic analysis, ARs were calculated for succulent peas and % CT information for several commodities was obtained from BEAD (Tier 3). Since the dietary exposure analysis already includes water exposure, no further calculations are required. The results of the chronic analysis indicate that the chronic dietary risk estimates for the general U.S. population and most population subgroups associated with the existing and proposed uses of bentazon do not exceed TRB•s level of concern. However, TRB's level of concern was exceeded for two subgroups: all infants (<1year) and non-nursing infants. **Thus, chronic aggregate risk estimates exceed TRB's level of concern.**

4.3 Short Term Aggregate Risk (food + water + residential)

In aggregating short-term risk, HED considered background chronic dietary exposure (food + drinking water) and short-term inhalation exposures (See Table 5). Since HIARC did not identify a dermal endpoint of concern for the short-term duration, only inhalation exposure estimates are relevant for the adult handler. Short-term inhalation exposure may occur for a homeowner treating turf and ornamentals on the same day.

The total short-term food and residential aggregate MOE value is ~19,000. As this MOE is greater than 1000, the short-term aggregate risk is below HED's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than HED's levels of comparison for bentazon in drinking water as a contribution to short-term aggregate exposure. Therefore, HED concludes with reasonable certainty that residues of bentazon in drinking water do not contribute significantly to the short-term aggregate human health risk at the present time.

Table 6. Short-Term Aggregate Risk Calculations

Population	Short-Term Scenario					
	NOAEL mg/kg/day	Target MOE[1]	Max Exposure[2] mg/kg/day	Average Dietary (food + water) Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]
Females 13-49 years old	100	1000	0.10	0.004968	0.000209	~19,000

[1] Basis for the target MOE : inter- and intra- species UFs totaling 100 + 10X FQPA SF
[2] Maximum Exposure (mg/kg/day) = NOAEL/Target MOE
[3] Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure]
[4] Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]

Although bentazon is a registered herbicide for use on turf and ornamentals, short-term non-dietary ingestion exposure for toddlers is not assessed since HIARC determined that there is no acute dietary or oral endpoint applicable to infants and children.

4.4 Intermediate-Term Aggregate Risk (food + water + residential)

In aggregating intermediate-term risk, HED considered background chronic dietary exposure (food + water) and intermediate-term, non-dietary oral and/or dermal exposures (see Table 6). For adults, post-application exposures may result from dermal contact with treated turf. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass.

The total food and residential intermediate-term aggregate MOEs are 1200-5300. As these values are greater than 1000, the intermediate-term food and residential aggregate risks for the US population and infants/children are below TRB's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than TRB's levels of comparison for bentazon in drinking water as a contribution to intermediate-term aggregate exposure. Therefore, TRB concludes with reasonable certainty that residues of bentazon in drinking water do not contribute significantly to the intermediate-term aggregate human health risk at the present time.

Table 7. Intermediate-Term Aggregate Risk Calculations

Population	Intermediate-Term Scenario					
	NOAEL mg/kg/day	Target[1] MOE	MAX Exposure[2] mg/kg/day	Average Food (food + water) Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]
All infants (<1 year)	13.1	1000	0.0131	0.004099	0.0059	1300
Non-nursing Infants	13.1	1000	0.0131	0.005059	0.0059	1200
Children 1-2 years	13.1	1000	0.0131	0.002834	0.0059	1500
Children 3-5 years	13.1	1000	0.0131	0.002367	0.0059	1600
Children 6-12 years	13.1	1000	0.0131	0.001565	0.0014	4400
Youth 13-19 years	13.1	1000	0.0131	0.001057	0.0014	5300
Adults 20-49 years	13.1	1000	0.0131	0.001221	0.0014	5000
Adults 50+ years	13.1	1000	0.0131	0.001263	0.0014	4900
Females 13-49 years	13.1	1000	0.0131	0.001203	0.0014	5000

[1] Basis for the target MOE : inter- and intra- species UFs totaling 100 x 10X (FQPA SF)
[2] Maximum Exposure (mg/kg/day) = NOAEL/Target MOE
[3] Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure]
[4] Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]

5.0 CUMULATIVE RISK

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 bentazon and any other substances and bentazon 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 bentazon 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/.

6.0 OCCUPATIONAL EXPOSURE

6.1 SUMMARY OF PROPOSED NEW USE PATTERNS

PEACH: The product proposed for use is the registered product Basagran® herbicide (EPA Reg. No. 7969-45) which is a 4.0 lb active ingredient per gallon liquid. It is to be applied at the rate of 2 pints / A (1.0 lb a.i./A). There is a maximum of 4 pints / A (2.0 a.i./A) per season. The minimum application interval is 14 days. Applications are directed to the orchard floor. There is a 14 day PHI. It may not be applied through any type of irrigation system. There is a 48 hour

restricted entry interval.

Table 8 Summary of Proposed Use Pattern for Bentazon on Peach.

Formulation	Basagran® herbicide, Reg. No. 7969-45, (4.0 lb a.i./gal)
Site	peach
Pest	Broadleaf weeds
Application Method	Ground boom
Application Rate (max)	1.0 lb a.i./A
Number of Applications	2 per crop season
Retreatment Interval	14 days
Preharvest Interval (PHI)	14 days
Restricted Entry Interval (REI)	48 hours
Manufacturer	BASF Corporation

The Basagran® label directs occupational pesticide handlers to wear long-sleeved shirt, long pants, shoes plus socks and waterproof gloves.

6.2 HANDLER EXPOSURE

On 10 JUNE 1999, the HED HIARC met to discuss the adequacy of the toxicology database for bentazon (DP Barcode: 255923, J. Kidwell, 11/15/99). At that meeting dermal and inhalation toxicological endpoints were identified for use in risk assessment.

A short-term duration (1 - 30 days) dermal toxicological endpoint was NOT identified. The committee stated "No systemic toxicity was seen at the Limit-Dose in a 21 day dermal toxicity study in rats." However an intermediate-term duration dermal toxicological endpoint was identified (No Observable Adverse Effect Level/NOAEL = 13.1 mg a.i./kg bw/day). The toxic effect seen were the presence of feces with red areas seen in dogs at weeks, 4, 6, and 12 from a 1 year feeding study. A dermal absorption factor of 2.0 % was identified.

A short-term inhalation toxicological endpoint was identified from a developmental study in the rat. The NOAEL is 100 mg a.i./kg bw/day and the effects seen were increased postimplantation loss, skeletal variations, and reduced weight of fetuses surviving to day 21. Since the effects seen in the developmental study are fetal effects, a body weight of 60 kg is used to calculate daily dose of exposure.

An intermediate-term inhalation toxicological endpoint was also identified. The NOAEL is 13.1 mg a.i./kg bw/day identified from a 1 year feeding study in the dog where the effects seen were the presence of feces with red areas seen in dogs at 4, 6, and 12 weeks. The intermediate-term inhalation effects are the same as are identified for intermediate-term duration dermal exposures.

For risk assessment purposes, the intermediate-term dermal and inhalation exposures will be summed and then used to calculate Margin of Exposure (MOE). See Table 8 for a summary of exposures and risks to occupational pesticide handlers.

Since no short-term, dermal toxicological endpoint was identified, only MOEs for short-term inhalation are presented. It is unlikely that grower ■handlers• would experience intermediate-term exposures. However, commercial applicators may be exposed to intermediate-term exposures, so the intermediate dermal plus inhalation MOEs are presented.

Table 9. Estimated Handler Exposure and Risk from the Use of Bentazon on Peach and Nectarine

Unit Exposure[1] mg a.i./lb handled	Applic. Rate[2] lb a.i./A	Units Treated[3] A/day	Average Daily Dose[4] mg a.i./kg bw/day	Short-term inhalation MOE[5]	COMBINED Intermediate Term MOE[5]
Mixer/Loader - Liquid - Open Pour					
Dermal: SLNG 2.9 HC SLWG 0.023 HC Inhal 0.0012 HC	1.0	40	Dermal: No Gloves 0.039 With Gloves 0.00031 Inhal 0.0008	125,000	No Gloves 329 With Gloves 11,800
Applicator - Ground Boom - Open Cab					
Dermal: SLNG 0.014 HC SLWG 0.014 MC Inhal 0.00074 HC	1.0	40	Dermal: NG 0.00019 WG 0.00019 Inhal 0.00049	204,000	No Gloves 19,264 With Gloves 19,264

1. Unit Exposures are taken from "PHED SURROGATE EXPOSURE GUIDE", Estimates of Worker Exposure from The Pesticide Handler Exposure Database Version 1.1, August 1998. Dermal: SLNG = Single Layer Work Clothing **No Gloves**; SLWG = Single Layer Work Clothing **With Gloves**; Inhal. = Inhalation. Units = mg a.i./pound of active ingredient handled. Data Confidence: LC = Low Confidence, MC = Medium Confidence, HC = High Confidence.
2. Application Rate. = Taken from proposed amendments to Basagran label
3. Units Treated are taken from "Standard Values for Daily Acres Treated in Agriculture"; SOP No. 9.1. Science Advisory Council for Exposure; Revised 5 July 2000;
4. Average Daily Dose = Unit Exposure * Applic. Rate * Units Treated * 0.02 (2.0 % dermal absorption - assume 100 % inhalation absorption) ÷ Body Weight (60 kg).
5. MOE = Margin of Exposure = No Observable Adverse Effect Level (NOAEL) ÷ ADD. For short-term duration exposures, only inhalation risk is shown. For intermediate-term duration exposures, dermal and inhalation exposures are summed, then divided into the NOAEL.
Short-term duration exposure inhalation NOAEL = 100.0 mg a.i./kg bw/day. There is NO short-term dermal endpoint.
Intermediate-term duration exposure dermal and inhalation NOAEL = 13.1 mg a.i./kg bw/day

6.3 POST-APPLICATION WORKER EXPOSURE

Typically, there is the possibility of post-application exposure of agricultural workers to dislodgeable pesticide residue. This is due largely to contact with treated surfaces i.e., foliage etc. In this case, the application is directed to the orchard floor for broadleaf weed control. There is no need for workers to contact the orchard floor. Scouting for pesticide treatment efficacy may take place however, that would not result in significant exposure to a crop advisor or "scout". The Basagran® label lists a 48 hour restricted entry interval. Scouting for efficacy

is not likely to occur before that time. There is a 14 day preharvest interval. The proposed use does not exceed TRB's level of concern.

7.0 DATA NEEDS/LABEL REQUIREMENTS

7.1 Chemistry

Multiresidue testing using the FDA multiresidue protocols.

7.2 Toxicology

< *none*

7.3 Occupational Exposure

< *none*

cc: D. Rate (TRB), W. Cutchin (TRB), M. Dow (RAB1), J. Redden (TRB), D.Rosenblatt (MUIERB), S. Brothers (MUIERB)
RDI: W. Cutchin (02/10/06)

ATTACHMENT 1 - Hazard Identification Assessment Review Committee Report
(*Available Electronically*)

ATTACHMENT 2 - FQPA Safety Factor Committee Report (*Available Electronically*)

ATTACHMENT 3 - Codex Forms

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: 3-isopropyl-1-methyl-2,	Common Name: Bentazon	X Proposed tolerance Reevaluated tolerance Other	Date: 06/08/05

Codex Status (Maximum Residue Limits)	U. S. Tolerances
No Codex proposal step 6 or above X No Codex proposal step 6 or above for the crops requested	Petition Number: 2E6501 DP Barcode: D315268 Other Identifier:
Residue definition (step 8/CXL): sum of bentazon, 6-hydroxybentazon, and 8-hydroxybentazone, expressed as bentazon. (NO MRLs for peach or stone fruit)	Reviewer/Branch: Rate/TRB
	Residue definition: Bentazon 6-OH-bentazon 8-OH-bentazon

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		peach	0.05

Limits for Canada	Limits for Mexico
No Limits X No Limits for the crops requested	No Limits X No Limits for the crops requested
Residue definition: bentazon, including 6-hydroxybentazon, and 8-hydroxybentazon	Residue definition: Bentazon

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions:
S.Funk, 08/23/2005