

Imidacloprid

Human-Health Risk Assessment

DP# 375406

1

13

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**



OFFICE OF PREVENTION, PESTICIDES,
HEALTH EFFECTS DIVISION AND TOXIC SUBSTANCES
• SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM**Date:** 16-MAR-2010

SUBJECT: **Imidacloprid:** Revised Human-Health Risk Assessment for Proposed Section 3 Seed Treatment Uses on Bulb Vegetables (Crop Group 3); Cereal Grains (Crop Group 15); Root and Tuber Vegetables, Except Sugar Beet (Crop Subgroup 1B); Tuberos and Corm Vegetables (Crop Subgroup 1C); Leafy Vegetables, Except *Brassica* (Crop Subgroup 4A); *Brassica* Vegetables (Crop Group 5); Fruiting Vegetables (Crop Group 8); Cucurbit Vegetables (Crop Group 9), and Residential Crack and Crevice and Bed-Bug Uses.

PC Code: 129099**Decision No.:** 399586**Petition Nos.:** 8F7414, 8F7415**Risk Assessment Type:** Single Chemical Aggregate**TXR No.:** NA**MRID No.:** NA**DP Barcode:** D375406**Registration Nos.:** 264.xxx, 264-827**Regulatory Action:** Section 3 Registration**Case No.:** NA**CAS No.:** 138261-41-3**40 CFR:** §180.472

FROM: George F. Kramer, Ph.D., Senior Chemist
Jennifer R. Tyler, Chemist
Robert Mitkus, Ph.D., Toxicologist
Kelly Lowe, Environmental Scientist
Mary Clock-Rust, Biologist
Risk Assessment Branch 1 (RAB1)
Health Effects Division (HED; 7509P)

THROUGH: Dana M. Vogel, Branch Chief
RAB1/HED (7509P)

TO: Kable Davis/Venus Eagle, RM Team 05
Registration Division (RD; 7505P)

NOTE: This document supersedes Memo, G. Kramer, 24-DEC-2009 (DP# 371304). The assessment has been updated to include a revised assessment of the registered pet uses.

The HED of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. The RD of OPP has requested that HED 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 the following: 1) the

Review in file
3/17/2010
RW

proposed new tolerances for the active ingredient (ai) imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine) on bulb vegetables (crop group 3) and cereal grains (crop group 15); 2) the proposed new seed-treatment uses for imidacloprid on root and tuber vegetables, except sugar beet (crop subgroup 1B); tuberous and corm vegetables (crop subgroup 1C); leafy vegetables, except *Brassica* (crop subgroup 4A); *Brassica* vegetables (crop group 5); fruiting vegetables (crop group 8); and cucurbit vegetables (crop group 9); and 3) proposed residential uses of imidacloprid to treat bed bugs. A summary of the findings and an assessment of human-health risk resulting from the aforementioned uses are provided in this document. The risk assessment, residue chemistry data review, and dietary exposure assessment were provided by Jennifer Tyler and George Kramer (RAB1), the hazard characterization and endpoint selection by Robert Mitkus (RAB1), and occupational exposure assessment by Kelly Lowe (RAB1), and the drinking water exposure assessment by José Melendez of the Environmental Fate and Effects Division (EFED).

TABLE OF CONTENTS

INTRODUCTION	4
1.0 EXECUTIVE SUMMARY	5
2.0 SUMMARY OF REGISTERED AND PROPOSED USES	12
3.0 HAZARD CHARACTERIZATION/ASSESSMENT	15
3.1 MAMMALIAN TOXICOLOGY	15
3.2 FQPA CONSIDERATIONS	15
3.3 TOXICITY ENDPOINT SELECTION	17
3.4 ENDOCRINE DISRUPTION	19
4.0 PUBLIC HEALTH AND PESTICIDE EPIDEMIOLOGY DATA	20
4.1 INCIDENT REPORTS	20
5.0 DIETARY EXPOSURE/RISK CHARACTERIZATION	20
5.1 FOOD RESIDUE PROFILE	20
5.2 DRINKING WATER RESIDUE PROFILE	23
5.3 DIETARY EXPOSURE AND RISK	24
6.0 RESIDENTIAL (NON-OCCUPATIONAL) EXPOSURE/RISK CHARACTERIZATION	26
6.1 RESIDENTIAL HANDLER EXPOSURE	27
6.2 RESIDENTIAL POST-APPLICATION EXPOSURE	29
6.3 COMBINED RESIDENTIAL RISK ESTIMATES	35
7.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION	38
7.1 ACUTE AGGREGATE RISK	38
7.2 SHORT-TERM AGGREGATE RISK	38
7.3 INTERMEDIATE-TERM AGGREGATE RISK	39
7.4 CHRONIC AGGREGATE RISK	40
8.0 CUMULATIVE RISK CHARACTERIZATION/ASSESSMENT	40
9.0 OCCUPATIONAL EXPOSURE/RISK PATHWAY	41
9.1 OCCUPATIONAL HANDLER EXPOSURES AND RISKS	41
9.2 OCCUPATIONAL POST-APPLICATION EXPOSURES AND RISKS	45
9.3 REI	45
10.0 DATA NEEDS AND LABEL REQUIREMENTS	46
10.1 TOXICOLOGY	46
10.2 RESIDUE CHEMISTRY	46
10.3 OCCUPATIONAL AND RESIDENTIAL EXPOSURE	46
ATTACHMENT 1: TOXICITY PROFILE TABLES	48
ATTACHMENT 2: STRUCTURES OF IMIDACLOPRID METABOLITES	52
ATTACHMENT 3: IRLS SHEET	53
ATTACHMENT 4: OCCUPATIONAL HANDLER EXPOSURE AND RISK CALCULATIONS TABLES	54

Introduction

Bayer CropScience has submitted (1) a petition (PP# 8F7414) for the use of imidacloprid on bulb vegetables (crop group 3), (2) a request (PP# 8F7415) to include on the Sepresto 75 WS label the use of imidacloprid as a seed treatment on cereal grains (crop group 15), and (3) a request to add a residential bed-bug use to the Temprid™ SC Insecticide label.

Bayer has requested to add the bulb vegetable use to the following labels: Sepresto 75 WS [a water-soluble concentrate (WS) product containing both clothianidin and 18.75% imidacloprid as active ingredients (ai); EPA Reg. No. 264.xxx], and Gaucho® 550 SC [a soluble-concentrate (SC) formulation containing 42.8% imidacloprid as the ai; EPA Reg. No. 264-827]. *HED notes that this document pertains to the ai imidacloprid only.* In conjunction with this petition, a tolerance of 2.5 ppm has been requested for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on vegetable, bulb, group 3.

In addition, Bayer has submitted a request to include on the Sepresto 75 WS label the use of imidacloprid as a seed treatment on cereal grains (crop group 15). In conjunction with this petition, a tolerance of 0.05 ppm has been requested for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on cereal, grain, group 15. This proposal is based on the currently established tolerances of 0.05 ppm in/on grains of corn, sorghum, wheat, and barley. In conjunction with this petition, Bayer has requested the use of currently established tolerances, which were established based on foliar and/or soil applications, to support seed-treatment uses on the following raw agricultural commodities (RACs): root and tuber vegetables, except sugar beet (crop subgroup 1B); tuberous and corm vegetables (crop subgroup 1C); leafy vegetables, except *Brassica* (crop subgroup 4A); *Brassica* vegetables (crop group 5); fruiting vegetables (crop group 8); and cucurbit vegetables (crop group 9).

An assessment of proposed uses of Temprid™ SC Insecticide (Reg. No. 432-1483) for the control of bed bugs is included in this risk assessment document. In addition, an assessment of the currently registered indoor crack and crevice use of Temprid™ SC is included as this use has not been assessed previously.

The most recent human-health risk assessment was conducted by Alternative Risk Integration Assessment Team (ARIA) in RD in conjunction with Section 3 requests for use of imidacloprid on peanut, proso millet, pearl millet, oat, kava, globe artichoke, caneberries, wild raspberry, and soybeans (Memo, W. Cutchin *et al.*, 5/14/07; D33773). A human-health Scoping Document in support of Registration Review was also recently conducted (Memo, J. Tyler, 12/3/08; D353984). The following information from the 5/14/07 risk assessment can be applied directly to this action:

- Identification of Active Ingredient and Physical and Chemical Properties (Sections 2.2 and 2.3; p. 17).
- Pesticide Metabolism and Environmental Degradation (Sections 5.1.1-5.1.7; pp. 41-45).

This document contains only those aspects of the risk assessment that are affected by the addition of the proposed new uses of imidacloprid.

1.0 Executive Summary

Imidacloprid is a systemic insecticide registered to control soil insects, sucking insects, chewing insects, and termites. It is effective against the larval, nymphal, and adult stages. The primary mode of action in insects is the disruption of the nervous system by acting as an inhibitor at nicotinic acetylcholine receptors. Imidacloprid blocks the signals that are induced by acetylcholine at the post-synaptic membrane, resulting in nerve function impairment. Imidacloprid is registered for use on several agricultural products, ornamental turf/plant products, seed treatments, pet care products, as well as structural pest products. Imidacloprid is being evaluated as part of a joint review with Canada.

Imidacloprid will be formulated as a WS formulation containing both clothianidin and 18.75% imidacloprid (Sepresto 75 WS; EPA Reg. No. 264.xxx), a SC formulation containing 42.8% imidacloprid (Gaucho[®] 550 SC; EPA Reg. No. 264-827), and a SC formulation containing both beta-cyfluthrin and 21% imidacloprid (Temprid[™] SC; EPA Reg. No. 432-1483). *HED notes that this document pertains to the ai imidacloprid only.*

Hazard Assessment: Imidacloprid has low acute toxicity via the dermal and inhalation routes and moderate acute toxicity via the oral route. It is not an eye or dermal irritant and is not a dermal sensitizer. The nervous system is the primary target organ of imidacloprid. Nervous system effects evidenced as changes in clinical signs and functional-observation battery (FOB) assessments were seen in rat acute and subchronic neurotoxicity studies. Also, in the rat developmental neurotoxicity (DNT) study, a decrease in the caudate/putamen width was noted in female pups. Retinal atrophy was seen in high-dose females in the rat combined chronic toxicity/carcinogenicity study. No nervous system effects were noted in the mouse carcinogenicity or the reproduction and developmental studies or in the rabbit dermal or rat inhalation studies. The dog was less sensitive than rodents to the effects of imidacloprid. The rabbit appeared to be very sensitive as there was increased mortality in the oral developmental study at the highest dose tested. Increased incidence of mineralized particles in the thyroid colloid was noted in the rat combined chronic toxicity/carcinogenicity study. Body-weight decrements were noted in the rat and/or mouse chronic and carcinogenicity studies, the rat subchronic neurotoxicity study, and the developmental, DNT and reproduction studies. No effects were observed in the rabbit dermal or rat inhalation studies. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies, and there is no concern for mutagenicity. There was no evidence of increased qualitative or quantitative susceptibility of rats or rabbits to *in utero* exposure to imidacloprid and no evidence of qualitative or quantitative increased susceptibility of rat offspring in the reproduction study. There was evidence of an increased qualitative susceptibility in the rat DNT study. At the highest dose tested, maternal effects consisted largely of slight decreases in food consumption and body-weight gain during early lactation, while pup effects included decreased body weight, decreased motor activity, decreased caudate/putamen width in females only [postnatal days (PNDs) 11 and adult], and slight changes in performance in the water maze in males only at the same dose.

Dose-Response Assessment and Food Quality Protection Act (FQPA) Decision: The HED Hazard Identification Assessment Review Committee (HIARC) met on 10/8/02 to select endpoints for risk assessment and to evaluate the potential for increased susceptibility of infants and children from exposure to imidacloprid according to the February 2002 OPP 10X guidance document. This was a re-evaluation of the toxicology database subsequent to the initial evaluation by the HIARC on 9/11/97. The FQPA Safety Factor (SF) was reduced to 1X based on toxicological considerations by the HIARC (TXR # 0051292, 10/31/02), the conservative residue assumptions used in the dietary and residential exposure risk assessments, and the completeness of the residue chemistry and environmental fate databases (evaluated by the risk assessment team). The imidacloprid risk assessment team recommends that the 10X FQPA SF for the protection of infants and children be reduced to 1X for all exposure scenarios except acute dietary (all populations). The recommendation is based on the following:

- There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study.
- There is evidence of increased qualitative susceptibility in the rat DNT study, but the concern is low since: 1) the effects in pups are well-characterized with a clear no-observed-adverse-effect-level (NOAEL); 2) the pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in pups and dams; and, 3) the doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the DNT study. Therefore, there are no residual uncertainties for pre-/post-natal toxicity in this study.
- Except for an immunotoxicity study, the toxicological database is complete for FQPA assessment. There was no evidence of immunotoxicity in the database for imidacloprid.
- The *acute* dietary food exposure assessment utilizes existing and proposed tolerance-level residues and 100% crop treated (CT) information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- The *chronic* dietary food exposure assessment utilizes existing and proposed tolerance-level residues and % CT data verified by the Biological and Economic Analysis Division (BEAD) for several existing uses. For all proposed uses, 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.
- The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters, which are designed to provide conservative, health-protective, high-end estimates of water concentrations, which will not likely be exceeded.
- The residential handler assessment is based upon the residential standard operating procedures (SOPs) in conjunction with chemical-specific study data in some cases and Pesticide Handlers Exposure Database (PHED) unit exposures in other cases. The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk.
- A 3X FQPA SF was retained in the form of a uncertainty factor due to extrapolation from a lowest-observed-adverse-effect-level (LOAEL) in the absence of a NOAEL (UF_L) for the acute dietary (all populations) exposure scenario, since a NOAEL was not observed in the acute neurotoxicity study in rats. A 3X uncertainty factor was judged to be adequate (as opposed to a 10X) by the HIARC for the following reasons: 1) the LOAEL (42 mg/kg) is comparable to the LOAELs seen in adults in the developmental rat study (30 mg/kg/d) and the two-generation reproduction study [47/52 mg/kg/d (male/female)] and in the offspring in the DNT study (55 mg/kg/d); 2) the extrapolated NOAEL of 14 mg/kg ($42/3 = 14$) is comparable to the NOAEL of 20 mg/kg/d established in the offspring in the DNT; and 3) the neurotoxic effects in this study showed a good dose response, which resulted in minimal effects on motor activity and locomotor activity at the LOAEL (DP Num: 286101, J. Tyler, 3/4/03).

Risk assessments were conducted for the following specific exposure scenarios listed below. The acute population-adjusted dose (aPAD) was calculated by dividing the acute point of departure (aPOD), in this case the LOAEL from the acute neurotoxicity study, by 300 (10X for

interspecies extrapolation, 10X for intraspecies variation, and 3X UF_L for the use of a LOAEL due to the lack of a NOAEL). The chronic PAD (cPAD) was calculated by dividing the chronic POD (cPOD), in this case the NOAEL from the chronic toxicity study in rats, by 100 (10X for interspecies extrapolation and 10X for intraspecies variation). Since the FQPA SF has been reduced to 1X, the aPAD and cPAD are not further adjusted. Since oral studies were selected for all durations of dermal and inhalation exposure, a 7% dermal-absorption factor and a 100% inhalation-absorption factor were used in the route-to-route extrapolation. The level of concern for occupational dermal and inhalation exposures are for margins of exposure (MOEs) <100. For the occupational exposure assessment, dermal and inhalation exposure estimates can be combined because of the use of the same toxicity endpoint (decreased body-weight gain) from the same study (oral rat developmental toxicity study) was identified for risk assessment. The level of concern for residential oral, dermal and inhalation exposures are for MOEs <100. Short-term oral, dermal and inhalation exposure estimates can be aggregated because of the use of the same toxicity endpoint (decreased body-weight gain) from the same study (oral rat developmental toxicity study).

<u>Exposure Scenario</u>	<u>Dose</u>	<u>Endpoint</u>	<u>Effect/Study</u>
Acute dietary	LOAEL = 42 mg/kg/day	aPAD = 0.14 mg/kg/day	Decreased motor and locomotor activities/Acute neurotoxicity study in rats
Chronic dietary	NOAEL = 5.7 mg/kg/day	cPAD = 0.057 mg/kg/day	Increased incidence of mineralized particles in the thyroid colloid/chronic toxicity study in rats
Short-term incidental oral	Oral NOAEL = 10 mg/kg/day	Target MOE = 100 (residential)	Decreased body-weight gain and decreased corrected body-weight gain in maternal animals/ Developmental toxicity study in rats
Short-term dermal	Oral NOAEL = 10 mg/kg/day	Target MOE = 100 (occupational and residential)	
Short-term inhalation	Oral NOAEL = 10 mg/kg/day	Target MOE = 100 (occupational and residential)	
Intermediate-term incidental oral	Oral NOAEL = 9.3 mg/kg/day	Target MOE = 100 (residential)	LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain/ Subchronic neurotoxicity study in rats
Intermediate-term inhalation	Oral NOAEL = 9.3 mg/kg/day	Target MOE = 100 (occupational and residential)	LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain/ Subchronic neurotoxicity study in rats
Intermediate-term dermal	Oral NOAEL = 9.3 mg/kg/day	Target MOE = 100 (occupational and residential)	LOAEL = 63.3 mg/kg/day, based upon decreased body weight gain/Subchronic neurotoxicity study in rats

Residue Chemistry and Drinking Water Assessments: The residue chemistry and drinking water databases are adequate to assess potential human exposure to imidacloprid. The nature of imidacloprid residues in plants and livestock is adequately understood. The residue of concern in plants and livestock is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, as specified in 40 CFR §180.472. The residues of concern in drinking water are imidacloprid and the following degradates: imidacloprid urea, imidacloprid guanidine, and imidacloprid olefin.

Adequate crop field trial data have been submitted to support the proposed uses of imidacloprid. For bulb vegetables, the data reflect the maximum rates and minimum preharvest intervals

(PHIs) requested and have sufficient geographic representation to support tolerances. For the remaining uses, the previously submitted and reviewed crop field trial data are adequate to support the proposed seed-treatment uses. All crop field trial studies are supported by adequate storage stability data. Adequate processing data are available, and no new tolerances for processed commodities are needed. As no new tolerances are needed for the other proposed seed-treatment uses, the currently established tolerances on livestock are adequate. The rotational crop restrictions are adequate and are supported by available rotational crop data.

EFED provided Tier 1 estimated drinking water concentrations (EDWCs) for surface water [using FQPA Index Reservoir Screening Tool (FIRST)] and groundwater [using Screening Concentration in Ground Water (SCI-GROW)] for imidacloprid and its degradates (imidacloprid urea, imidacloprid guanidine, and imidacloprid olefin). Water residues were incorporated in the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID™; ver. 2.03) into the food categories “water, direct, all sources” and “water, indirect, all sources.” The acute (peak) and chronic (annual average) EDWCs, based on the citrus use pattern, are 36.0 ppb and 17.2 ppb, respectively. The SCI-GROW generated EDWC is 2.09 ppb of imidacloprid.

Dietary (Food and Drinking Water) Exposure Estimates: Acute and chronic dietary exposure analyses were conducted using the DEEM-FCID™ program, which incorporates consumption data from the United States Department of Agriculture’s (USDA’s) Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996/1998. For acute and chronic dietary risk estimates, HED’s level of concern is for estimates that exceed 100% aPAD or cPAD, respectively.

An unrefined, acute dietary exposure assessment using tolerance-level residues and assuming 100% CT for all registered and proposed commodities was conducted for the general U.S. population and various population subgroups. Exposure to drinking water was incorporated directly in the dietary assessment using the acute (peak) concentration for surface water generated by the FIRST model, 36.0 ppb. This assessment indicates that the acute dietary exposure estimates are below HED’s level of concern, <100% aPAD, at the 95th exposure percentile for the general U.S. population and all other population subgroups. The acute dietary exposure is estimated for the U.S. population at 28% of the aPAD and the most highly exposed population subgroup, children 1-2 years old, at 70% of the aPAD.

A partially refined, chronic dietary exposure assessment (using tolerance-level residues for all registered and proposed commodities, and %CT information for some commodities) was conducted for the general U.S. population and various population subgroups. Exposure to drinking water was incorporated directly into the dietary assessment using the chronic (annual average) concentration for surface water generated by the FIRST model, 17.2 ppb. This assessment concludes that the chronic dietary exposure estimates are below HED’s level of concern (<100% cPAD) for the general U.S. population and all population subgroups. The chronic dietary exposure is estimated for the U.S. population at 11% of the cPAD and the most highly exposed population subgroup, children 1-2 years old, at 32% of the cPAD.

Residential Exposure Estimates: Imidacloprid is currently registered for use on residential lawns and turf (including golf courses), ornamental plantings, pets, and indoor and outdoor residential sites, including pre-and post construction termiticide and wood preservative.

In this action, new residential uses are proposed on mattresses for bed-bug control. In addition, use of imidacloprid as a crack and crevice treatment is included in this document as these residential uses have not been previously evaluated and a revised pet assessment has been included. According to the proposed product label for Temprid™ SC Insecticide, the use of this product is intended for pest management professionals and commercial use only; however, the product is not a RUP and could potentially be used by homeowners. Therefore, both residential handler and post-application assessments for these uses have been conducted.

In this document, short- and intermediate-term residential handler and post-application risks were assessed. Long-term residential exposure is not expected for imidacloprid. Short- and intermediate-term estimates of exposure and risk for residents who treat their homes (handlers) result in MOEs that are greater than 100 and therefore, not of concern. HED also assessed potential short- and intermediate-term post-application risk based on use of imidacloprid on mattresses for bed bug control and as an indoor crack and crevice treatment. For the bed-bug use, dermal post-application risk is not of concern (i.e., MOEs >100) for both adults and toddlers. For the crack and crevice use, dermal, inhalation and incidental oral (toddlers only) post-application risk estimates are not of concern (i.e., MOEs >100) for both adults and toddlers. Even when exposures from the bed-bug use and the crack and crevice use were combined, post-application risk estimates for adults and toddlers were not of concern (i.e., MOEs >100). The combined residential exposure for the bed-bug and crack and crevice treatment uses is higher than that for other residential uses of imidacloprid; therefore, these exposures were combined with dietary and drinking water exposure in aggregate risk assessments.

Aggregate Exposure Scenarios and Risk Conclusions: For the proposed uses, human-health aggregate risk assessments have been conducted for the following exposure scenarios: acute aggregate exposure (food + drinking water), short-term aggregate exposure (food + drinking water + residential), intermediate-term aggregate exposure (food + residential + drinking water) and chronic aggregate exposure (food + drinking water). Residential long-term exposure is not expected based on the use pattern. A cancer aggregate risk assessment was not performed because imidacloprid is not carcinogenic. All potential exposure pathways were assessed in the aggregate risk assessment as a conservative, health-protective measure. All aggregate risk estimates are not of concern to HED for the scenarios listed above.

Occupational Handler Exposure Estimates: Occupational handler exposure is expected for individuals involved in commercial seed and seed-piece treatment, on-farm seed treatment, planting treated seeds, performing soil-directed treatment of bulb vegetables, and treating indoor residences for household pests and bed bugs. Handler risks were assessed using surrogate unit exposures from PHED, the Outdoor Residential Exposure Task Force (ORETF), and the HED Science Advisory Council for Exposure (ExpoSAC) Policy 14: SOPs for Seed Treatment. Values for amount handled per day are based on ExpoSAC Policy 3.0 and values for amount of seed treated or planted per day are based on ExpoSAC Policy 15: Amount of Seed Treated or Planted per Day.

Commercial Seed Treatment: For all vegetable crops, all seed-treatment handler scenarios assessed resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs \geq 100) with either baseline attire (i.e., single layer of clothing, no gloves, no respirator) or with additional

personal-protective equipment (PPE; e.g., gloves, respirator). When assessed using the HED default of 5,500 pounds of seeds treated per day, most scenarios did not have risks of concern with the label-recommended PPE (i.e., single layer of clothing, gloves and a PF-5 respirator). However, for lettuce (head and leaf), cabbage, and broccoli, MOEs exceeded HED's level of concern unless engineering controls were used (i.e., water-soluble bags). When these scenarios are assessed using the proposed value of 500 pounds of seed treated per day, MOEs do not exceed HED's level of concern when chemical-resistant gloves are worn in addition to the baseline attire. **HED recommends that either water-soluble bags be required for the seed treatment product or that the label includes a restriction to 500 lb seed treated/day for all vegetable crops.**

For cereal grains and potato seed pieces, all seed-treatment handler scenarios resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100) with either baseline attire (i.e., single layer of clothing, no gloves, no respirator) or with additional PPE (e.g., gloves, respirator).

On-farm Seed Treatment: For cereal grains and potato seed pieces, all on-farm seed-treatment handler scenarios resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100) with either baseline attire (i.e., single layer of clothing, no gloves, no respirator) or with additional PPE (e.g., gloves, respirator).

Seed Planting: Risks from planting treated seeds resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100), when chemical-resistant gloves are worn in addition to baseline attire. Dermal unit exposure data are not available at the baseline level of mitigation for this scenario. **HED recommends that RD ensure that appropriate language is placed on the product label to include the appropriate PPE for planters of treated seed.**

Soil-directed Treatment - Bulb Vegetables: The results of the occupational handler exposure and risk assessment for bulb vegetables indicate that MOEs do not exceed HED's level of concern (i.e., MOEs ≥ 100) with either baseline attire (i.e., single layer of clothing, no respirator) or with the addition of gloves as recommended on the label.

Residential Crack and Crevice and Bed Bug Uses: Occupational handler exposure is expected for individuals applying imidacloprid in homes and to mattresses. All occupational handler scenarios assessed resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100) with either baseline attire (i.e., single layer of clothing, no gloves) or with additional PPE (e.g., gloves).

Occupational Post-application Exposure Estimates: Occupational post-application exposure is possible for both the agricultural and indoor residential uses of imidacloprid. For the uses associated with the Temprid™ SC Insecticide product for bed bugs and indoor pest control, HED believes the presence of commercial handlers in treated residential areas is minimal after application. Therefore, a post-application quantitative assessment for the commercial handlers for this product was not conducted.

For the agricultural uses of imidacloprid, HED assumes that inhalation exposures are minimal following outdoor applications of an active ingredient with low vapor pressure. Since the

proposed agricultural uses of imidacloprid are only in outdoor settings and imidacloprid has a low vapor pressure (4×10^{-7} mPa at 20°C), post-application inhalation exposures and risks were not assessed. Occupational dermal post-application risks to agricultural workers following the planting of treated seeds and soil-directed treatments to bulb vegetables were not assessed, since currently HED does not have data to assess post-application exposures to pesticides in the soil. Since no quantitative post-application assessment was completed for treated seeds or soil-directed treatments to bulb vegetables, the restricted-entry interval (REI) is based on the acute toxicity of imidacloprid, which is classified as Category IV for acute dermal toxicity and for skin and eye irritation potential. Imidacloprid is not a dermal sensitizer. Under the Worker Protection Standard (WPS) for Agricultural Pesticides, the default REI is 12 hours for active ingredients classified as acute toxicity categories III or IV for these routes of entry. The WPS allows workers to enter treated areas without restriction if there will be no contact with anything that has been treated with the pesticide. For purposes of seed treatment (once the seeds are planted) and soil-directed treatments, workers can enter during the REI, *provided* they do not contact the soil/media subsurface. Therefore, HED concurs with the 12-hour REI on the proposed label for seed treatment and for bulb vegetable treatments. **HED recommends that the appropriate language be placed on the product label (Section B) to include the REI following the planting of treated seed.**

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

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

Review of Human Research: This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the PHED, the ORETF and studies that were used in the seed treatment SOPs have been determined to require a review of their ethical conduct, have received that review, and have been determined to be ethical.

Recommendations for Tolerances:

PP# 8F7414: Provided revised Sections B and F are submitted and the products are reformulated into water-soluble bags, the available toxicology, occupational/residential, and residue chemistry databases support the establishment of a conditional registration and the following permanent tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent: 2.5 ppm in/on onion, green, subgroup 3-07B; and 0.15 ppm in/on onion, dry bulb, subgroup 3-07A.

PP# 8F7415: Provided revised Sections B and F are submitted and the products are reformulated into water-soluble bags, the available toxicology, occupational/residential, and residue chemistry databases support the establishment of a conditional registration and the proposed permanent tolerance of 0.05 ppm for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on grain, cereal, except rice, group 15.

In addition, the available databases are adequate to support seed-treatment uses for vegetable, root, except sugar beet, subgroup 01B; vegetable, tuberous and corm, subgroup 01C; vegetable, leafy, except *Brassica*, subgroup 04A; vegetable, *Brassica*, group 5; vegetable, fruiting, group 8; and vegetable, cucurbit, group 9. The currently established tolerances for these crops, which were established based on foliar and/or soil applications, are adequate.

The registration should be made unconditional following submission of a guideline immunotoxicity study.

In addition, HED recommends that either water-soluble bags be required for the seed treatment product or the label includes a restriction to 500 lb seed treated/day for all vegetable crops and that RD ensures that appropriate language is placed on the product label to include the appropriate PPE for planters of treated seed.

2.0 Summary of Registered and Proposed Uses

Imidacloprid is an insecticide registered for uses on a variety of agricultural crops for the control of many insects, including aphids, cucumber beetles and whiteflies (e.g., sweet potato or silverleaf whitefly). Imidacloprid is a member of the pyridylmethylamine class of compounds. Its mode of action is the disruption of the nervous system by acting as an inhibitor at nicotinic acetylcholine receptors. Imidacloprid blocks the signals that are induced by acetylcholine at the post-synaptic membrane, resulting in normal nerve function impairment.

Imidacloprid is currently registered for use on residential ornamental lawns, golf courses, and ornamental plantings (i.e., flowering plants, foliage plants, herbaceous perennial plants, and woody plant, shrubs and trees). In addition to the outdoor uses, imidacloprid is also registered for use indoors. In this action, residential uses are proposed on mattresses for bed-bug control. The Temprid™ SC Insecticide label instructs users to spray bugs and eggs directly if possible. For infected mattresses, the product is applied to box springs, bedsprings, interiors of bed frames

or headboards, as well as mattress tufts, seams, folds and edges (until moist). Also, use of imidacloprid as a crack and crevice treatment is included in this document as these residential uses have not been previously evaluated. For the crack and crevice uses, Temprid™ SC can be applied to cracks and crevices along baseboards, moldings, and furniture. According to the proposed product label for Temprid™ SC Insecticide, the use of this product is intended for pest management professionals and commercial use only; however, the product is not a RUP and could potentially be used by homeowners. Therefore, both residential handler and post-application assessments for these uses have been included in this document.

Tolerances are currently established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, under 40 CFR §180.472 in/on various plant and livestock commodities. Section 18 Emergency Exemption tolerances with expiration/revocation dates are established in/on plant commodities under 40 CFR §180.472(b), and indirect or inadvertent tolerances are established as a result of application of the pesticide to growing crops and other non-food crops under 40 CFR §180.472(d).

The petitioner has submitted draft labels for the Sepresto 75 WS (EPA Reg. No. 264-xxx), and Gaucho® 550 SC (EPA Reg. No. 264-827). A summary of the proposed use patterns is detailed in Table 2.1.

Table 2.1. Summary of Proposed Use Patterns.

Crop Group	Commodity	Trade Name (EPA Reg. No.)	Application, Timing, Type, Equipment	Maximum Single Application Rate			Max. No. Applications/Season	Maximum Seasonal Application Rate (lb ai/cwt) ³	PHI ⁴ (days)
				oz Sepresto/1000 seed	No. seeds/lb seed ¹	lb imidacloprid /cwt ²			
AGRICULTURAL USES									
PP# 8F7415									
Bulb Vegetables (CG 3)	All	Gauche [®] 550 SC (264-827)	Soil directed	0.5 lb ai/A			1	0.5 lb ai/A	21
	Onion (bulb)	Sepresto (264-xxx),	Seed treatment	0.011	113,500	1.5	1	1.5	NA
	Leek			0.0126	158,900	2.3	1	2.3	NA
	Onion (bunching)			0.0065	113,500	0.86	1	0.86	NA
PP# 8F7415									
Root and Tuber Vegetables (CG1B)	Radish	Sepresto (264-xxx)	Seed treatment	0.028	40,860	1.3	1	1.3	NA
	Carrot			0.0074	363,200	3.1	1	3.1	NA
Leafy Vegetables (CG 4A)	Lettuce (head)		Seed treatment	0.050	408,600	24	1	24	NA
	Lettuce (leafy)			0.040	499,400	23	1	23	NA
	Spinach			0.0098	44,764.4	0.51	1	0.51	NA
Brassica Vegetables (CG 5)	Cabbage		Seed treatment	0.074	143,918	12	1	12	NA
	Broccoli			0.0062	240,166	1.7	1	1.7	NA
Fruiting Vegetables (CG 8)	Tomato		Seed treatment	0.0062	154,814	1.1	1	1.1	NA
	Pepper			0.031	68,100	2.5	1	2.5	NA
Cucurbit Vegetables (CG 9)	Squash (winter)		Seed treatment	0.062	3,178	0.23	1	0.23	NA
	Squash (summer)	3,178			0.23	1	0.23	NA	
	Melon	20,884			1.5	1	1.5	NA	
	Cucumber	18,160			1.3	1	1.3	NA	
Cereal Grains, Except Rice (CG 15)		Seed treatment, slurry treatment	2.0 oz/100 lb seed	-	0.023	1	0.023	NA	
Potato		Seed treatment	0.35 oz/100 lb seed	-	0.0041	1	0.0041	NA	
RESIDENTIAL USES									
Temprid™ SC Insecticide									
Indoor Household Pests (Crack and crevice use)	Temprid™ SC Insecticide	Low-pressure handwand	0.075% spray (0.05% imidacloprid) = 0.27 fl oz product/gal = 0.004 lb ai/gal			Not stated	NA	NA	
			0.15% spray (0.10% imidacloprid) = 0.54 fl oz/gal = 0.008 lb ai/gal						
Bed Bugs		Low-pressure handwand	0.075% spray (0.05% imidacloprid) = 0.27 fl oz product/gal = 0.004 lb ai/gal			Not stated	NA	NA	

- Information taken from an Excel spreadsheet entitled "Vegetable Rate Chart for Sepresto 75WS 1-21-2009" sent in an e-mail from J. Huang to V. Eagle on 1/21/09.
- lb Sepresto/cwt seed = (oz Sepresto/1000 seed)*[(seeds/lb of seed)/1000]*(1lb/ 16 oz)(100 lb cwt)]. lb imidacloprid/cwt seed = lb Sepresto/cwt seed*0.1875.
- Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than 0.5 lb imidacloprid/A/year.
- PHI = preharvest interval.

HED Conclusions: The use directions provided by the petitioner are adequate to allow evaluation of the residue data relative to the proposed seed-treatment uses.

3.0 Hazard Characterization/Assessment

3.1 Mammalian Toxicology

Methylene-labeled imidacloprid was rapidly absorbed with approximately 90% of the administered dose being eliminated within 24 hours and 96% within 48 hours. Urinary excretion was the major route of elimination (70-80% of recovered radioactivity), with a lesser amount eliminated in feces (17-25% of recovered radioactivity). Biliary excretion was a major contributor to fecal radioactivity (36.6% vs. 4.8% of recovered radioactivity in bile-fistulated animals). Total tissue burden after 48 hours accounted for only approximately 0.5% of the recovered radioactivity, with major sites of accumulation being the liver, kidney, lung, skin, and plasma and minor sites being the brain and testes. There were two major evident routes of biotransformation. The first included an oxidative cleavage of the parent compound to give 6-chloronicotinic acid (6-CNA) and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second included the hydroxylation of imidazolidine followed by elimination of water of the parent compound to give NTN 35884.

Imidacloprid has low acute toxicity via the dermal and inhalation routes and moderate acute toxicity via the oral route. It is not an eye or dermal irritant and is not a dermal sensitizer. The nervous system is the primary target organ of imidacloprid. Nervous system effects evidenced as changes in clinical signs and FOB assessments were seen in rat acute and subchronic neurotoxicity studies. These effects included decreased motor and locomotor activities, tremors, gait abnormalities, increased righting reflex impairments and body temperature, and decreased number of rears and response to stimuli and decreases in forelimb and hindlimb grip strength. Also, in the rat DNT study, a decrease in the caudate/putamen width was noted in female pups. Retinal atrophy was seen in high-dose females in the rat combined chronic toxicity/carcinogenicity study. No nervous system effects were noted in the mouse carcinogenicity or the reproduction and developmental studies or in the rabbit dermal or rat inhalation studies.

The dog was less sensitive than rodents to the effects of imidacloprid. No effects were noted up to the highest dose tested in the chronic toxicity study in dogs. The rabbit appeared to be very sensitive as there was increased mortality in the oral developmental study at the highest dose tested. Increased incidence of mineralized particles in the thyroid colloid was noted in the rat combined chronic toxicity/carcinogenicity study. Body weight decrements were noted in the rat and/or mouse chronic and carcinogenicity studies, the rat subchronic neurotoxicity study, and the developmental, DNT and reproduction studies. No effects were observed in the rabbit dermal or rat inhalation studies. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies, and there was no concern for mutagenicity across a host of genotoxicity assays. On 11/10/93, the RfD/Peer Review Committee classified imidacloprid as a Group E chemical, "Evidence of non-carcinogenicity for humans," by all routes of exposure based upon lack of evidence of carcinogenicity in rats and mice.

3.2 FQPA Considerations

On 10/08/2002, the HED HIARC evaluated the potential for increased susceptibility of infants and children from exposure to imidacloprid according to the February 2002 OPP 10X guidance document. The HIARC concluded that the toxicology database was complete for FQPA purposes and that there are no residual uncertainties for pre-/post-natal toxicity (Memo, D. Nixon, 10/31/02; TXR NO. 0051292). Based on the on the hazard data, the HIARC recommended the FQPA SF be reduced to 1X. RAB1 reaffirmed the HIARC's decision and the FQPA SF was reduced to 1X for all exposure scenarios except acute dietary (all populations) in accordance with HED's Hot Sheet #30 ("Application of the FQPA safety factor in FFDCA risk assessments and additional uncertainty factors in FIFRA risk assessments"). The recommendation is based on the following:

- There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study.
- There is evidence of increased qualitative susceptibility in the rat DNT study, but the concern is low since: 1) the effects in pups are well-characterized with a clear NOAEL; 2) the pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in pups and dams; and, 3) the doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the DNT study. Therefore, there are no residual uncertainties for pre-/post-natal toxicity in this study.
- The toxicological database is complete for FQPA assessment.
- The *acute* dietary food exposure assessment utilizes existing and proposed tolerance-level residues and 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- The *chronic* dietary food exposure assessment utilizes existing and proposed tolerance-level residues and % CT data verified by BEAD for several existing uses. For all proposed uses, 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.
- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded.
- The residential handler assessment is based upon the residential SOPs in conjunction with chemical-specific study data in some cases and PHED unit exposures in other cases. The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to imidacloprid.

A 3X FQPA SF was retained in the form of a UF_L (uncertainty factor due to extrapolation from a LOAEL in the absence of a NOAEL) for the acute dietary (all populations) exposure scenario, since a NOAEL was not observed in the acute neurotoxicity study in rats. A 3X uncertainty factor was judged to be adequate (as opposed to a 10X) by the HIARC for the following reasons: 1) the LOAEL (42 mg/kg) is comparable to the LOAELs seen in adults in the developmental rat study (30 mg/kg/d) and the two-generation reproduction study [47/52 mg/kg/d (male/female)] and in the offspring in the DNT study (55 mg/kg/d); 2) the extrapolated NOAEL of 14 mg/kg (42/3 = 14) is comparable to the NOAEL of 20 mg/kg/d established in the offspring in the DNT; and, 3) the neurotoxic effects in this study showed a good dose response which resulted in minimal effects on motor activity and locomotor activity at the LOAEL (DP# 286101, J. Tyler, 3/4/03).

The toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does

not directly target the immune system. An immunotoxicity study is required as a part of new data requirements in the 40 CFR Part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment. Therefore, a database uncertainty factor (UF_{DB}) is not needed to account for lack of this study.

3.3 Toxicity Endpoint Selection

A summary of the doses and endpoints chosen by the HIARC (2002) for human-health risk assessment is found in Table 3.3.1.

Table 3.3.1. Summary of Toxicological Dose and Endpoints for Imidacloprid for Use in Human-Health Risk Assessment.			
Exposure Scenario	Dose Used in Risk Assessment, Safety Factors	RfD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary <u>all populations</u>	LOAEL = 42 mg/kg/day $UF_A = 10X$ $UF_H = 10X$ FQPA SF = 3X	aRfD = aPAD = 0.14 mg/kg	Acute neurotoxicity – rat LOAEL = 42 mg/kg, based upon the decrease in motor and locomotor activities observed in females.
Chronic Dietary <u>all populations</u>	NOAEL = 5.7 mg/kg/day $UF_A = 10X$ $UF_H = 10X$ FQPA SF = 1X	cRfD = cPAD = 0.057 mg/kg/day	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.
Short-Term Oral (1-30 days)	NOAEL = 10 mg/kg/day $UF_A = 10X$ $UF_H = 10X$ FQPA SF = 1X	LOC for MOE = 100 (Residential)	Developmental toxicity – rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body-weight gain and corrected body-weight gain.
Intermediate-Term Oral (1-6 months)	NOAEL = 9.3 mg/kg/day $UF_A = 10X$ $UF_H = 10X$ FQPA SF = 1X	LOC for MOE = 100 (Residential)	Subchronic neurotoxicity – rat LOAEL = 63.3 mg/kg/day, based upon decreased body-weight gain.
Short-Term Dermal (1-30 days)	NOAEL = 10 mg/kg/day $UF_A = 10X$ $UF_H = 10X$ (dermal-absorption rate = 7.2%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X)	Developmental toxicity – rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body-weight gain and corrected body-weight gain.

Table 3.3.1. Summary of Toxicological Dose and Endpoints for Imidacloprid for Use in Human-Health Risk Assessment.			
Exposure Scenario	Dose Used in Risk Assessment, Safety Factors	RfD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Dermal (1-6 months)	NOAEL = 9.3 mg/kg/day UF _A = 10X UF _H = 10X (dermal-absorption rate = 7.2%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X)	Subchronic neurotoxicity – rat LOAEL = 63.3 mg/kg/day, based upon decreased body-weight gain.
Long-Term Dermal (> 6 months)	NOAEL = 5.7 mg/kg/day UF _A = 10X UF _H = 10X (dermal-absorption rate = 7.2%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X)	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.
Short-Term Inhalation (1-30 days)	NOAEL = 10 mg/kg/day UF _A = 10X UF _H = 10X (inhalation-absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X)	Developmental toxicity – rat Maternal LOAEL = 30 mg/kg/day, based upon decreased body-weight gain and corrected body-weight gain.
Intermediate-Term Inhalation (1-6 months)	NOAEL = 9.3 mg/kg/day UF _A = 10X UF _H = 10X (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X)	Subchronic neurotoxicity – rat LOAEL = 63.3 mg/kg/day, based upon decreased body-weight gain.
Long-Term Inhalation (>6 months)	NOAEL = 5.7 mg/kg/day UF _A = 10X UF _H = 10X (inhalation-absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF = 1X)	Combined chronic toxicity/carcinogenicity – rat LOAEL = 16.9 mg/kg/day, based upon increased incidence of mineralized particles in thyroid colloid in males.
Cancer (oral, dermal, inhalation)	Classified as Group E, "Evidence of non-carcinogenicity for humans."		

NOAEL = no-observed adverse-effect level, LOAEL = lowest-observed adverse-effect level, PAD = population-adjusted dose (a = acute, c = chronic) POD = point of departure, MOE = margin of exposure, LOC = level of concern, FQPA SF = FQPA Safety Factor, UF_L = extrapolation from a LOAEL in absence of a NOAEL, UF_A = inter-species extrapolation, UF_H = inter-individual variability

3.3.1 Level of Concern for MOE

Table 3.3.1.1. Summary of Levels of Concern for Risk Assessment.			
Route	Short-Term (1-30 Days)	Intermediate-Term (1-6 Months)	Long-Term (> 6 Months)
Occupational (Worker) Exposure			
Dermal	100	100	100
Inhalation	100	100	100
Residential Exposure			
Dermal	100	100	100
Inhalation	100	100	100
Oral	100	100	100

3.3.2 Recommendation for Aggregate Exposure Risk

As per FQPA, 1996, when there are potential residential exposures to the pesticide, aggregate risk assessment must consider exposures from three major sources: oral, dermal and inhalation exposures. For short- and intermediate-exposure, oral, dermal and inhalation endpoints can be aggregated because of the use of oral equivalents and a common endpoint (decreased body-weight gain). For long-term exposure, oral, dermal and inhalation endpoints can be aggregated because of the use of oral equivalents and a common endpoint (thyroid toxicity).

3.3.3 Classification of Carcinogenic Potential

Imidacloprid has been classified as a Group E chemical, "Evidence of non-carcinogenicity for humans," by the HED RfD/Peer Review Committee (11/10/93).

3.4 Endocrine Disruption

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, and or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA is issuing test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Imidacloprid is among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. The Agency will review the EDSP Tier 1 data and any "other scientifically relevant information" submitted in response to test orders. Based on this review the Agency will determine the need for additional testing. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: <http://www.epa.gov/endo/>.

4.0 Public Health and Pesticide Epidemiology Data

4.1 Incident Reports

In conjunction with the Registration Review process, a summary report listing incidents for imidacloprid reported to the OPP Incident Data System (IDS) was provided (Memo, M. Hawkins, 8/27/08). The report represents incidents occurring in the U.S. from 2000 to the present for imidacloprid only. Approximately 400 incidents have been reported since 2000. The reported incidents will be screened in more detail during the development of the Final Work Plan (FWP) for imidacloprid.

5.0 Dietary Exposure/Risk Characterization

The residue chemistry data submitted in support of the proposed uses were summarized in the HED memorandum by J. Tyler (Memo, 7/30/09; DP# 357031). The EDWCs were provided in a memorandum by J. Melendez (Memo; 7/22/09). The acute and chronic dietary exposure assessment was completed in a HED memorandum by J. Tyler (Memo, 7/30/09; DP# 365444).

5.1 Food Residue Profile

Bayer CropScience has submitted a petition (PP# 8F7414) for the use of imidacloprid on bulb vegetables (crop group 3). Bayer has requested to add the bulb vegetable use to the following labels: Sepresto 75 WS (a WS product containing both clothianidin and 18.75% imidacloprid; EPA Reg. No. 264.xxx), and Gaucho[®] 550 SC (a SC formulation containing 42.8% imidacloprid; EPA Reg. No. 264-827). In conjunction with this petition, a tolerance of 2.5 ppm has been requested for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on vegetable, bulb, group 3.

In addition, Bayer has submitted a request (PP# 8F7415) to include on the Sepresto 75 WS label the use of imidacloprid as a seed treatment on cereal grains (crop group 15). In conjunction with this petition, a tolerance of 0.05 ppm has been requested for the combined residues of

imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on cereal, grain, group 15. This proposal is based on the currently established tolerances of 0.05 ppm in/on grains of corn, sorghum, wheat, and barley. In conjunction with this petition, Bayer has requested the use of currently established tolerances, which were established based on foliar and/or soil applications, to support seed-treatment uses on the following RACs: root and tuber vegetables, except sugar beet (crop subgroup 1B); tuberous and corm vegetables (crop subgroup 1C); leafy vegetables, except *Brassica* (crop subgroup 4A); *Brassica* vegetables (crop group 5); fruiting vegetables (crop group 8); and cucurbit vegetables (crop group 9).

The nature of imidacloprid residues in plants and livestock is adequately understood. The residue of concern in plants and livestock is imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, as specified in 40 CFR §180.472.

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plant [Bayer Gas Chromatography/Mass Spectrometry (GC/MS) Method 00200] and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA petition method validations (PMVs), and the registrant has fulfilled the remaining requirements for additional raw data, method validation, independent laboratory validation (ILV), and an acceptable confirmatory method [high-performance liquid chromatography/ultraviolet (HPLC/UV) Method 00357] (Memos, F. Griffith, 6/18/93, D187911; 6/1/94, D202113; 6/8/94, D200233; 6/8/95, D213252; and 12/18/95, D221591).

Bayer Corporation previously submitted adequate multiresidue (MRM) recovery data for imidacloprid and the metabolites 5-hydroxy imidacloprid, imidacloprid olefin, des nitro imidacloprid and 6-CNA through Food and Drug Administration (FDA) Protocols A through E (Memos, F. Griffith, 6/18/93, D187911; 7/15/93, D193027; 6/8/94, D200233; and 6/22/94, D194206). Imidacloprid and its metabolites were not recoverable by these methods. The results of the MRM testing for imidacloprid were forwarded to FDA for inclusion in the Pesticide Analytical Method Volume I (PAM I) (Memo, F. Griffith, 7/15/93, D193005).

The available storage stability data are adequate to support the submitted residue field trial data. The maximum storage interval from collection to extraction was 248 days (8.3 months) for green onions and 328 days (11 months) for dry bulb onions. Residues of imidacloprid have been shown to be stable in a variety of RACs for up to 2 years (~728 days) of storage (Memo, F. Griffith, 6/8/95, PP#5F4480). Analysis of samples from the ¹⁴C-imidacloprid plant metabolism studies for corn, cotton, apples, and potatoes showed no loss of imidacloprid and its major metabolites during a period of 2 years of frozen storage (Memo, F. Griffith, 9/21/93, D185148).

No new ruminant or poultry feeding studies have been submitted with the subject petition. Permanent tolerances have been previously established for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as the parent, in/on the following livestock commodities: fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep at 0.3 ppm; milk at 0.1 ppm; eggs at 0.02 ppm; and meat, fat and meat byproducts of poultry at 0.05 ppm. There are no ruminant feed items associated with the bulb

vegetable crop group. As no new tolerances are needed for the other proposed seed-treatment uses, the currently established tolerances on livestock are adequate.

The number and locations of the crop field trials on bulb vegetables are in accordance with OPPTS Guideline 860.1500 for green onion, but not for dry bulb onions. The dry bulb onion trials were conducted in North American Free Trade Agreement (NAFTA) Growing Zones 1 (1 trial), 6 (2 trials), 10 (2 trials) and 11 (1 trial). OPPTS Guidelines recommend trials be conducted in Zones 1 (1 trial), 6 (1 trials), 8 (1 trial), 10 (2 trials) and 11 (1 trial). There were two dry bulb onion trials conducted in Uvalde, TX, which is located in Zone 6; however, the Study Report indicates that one of these trials was conducted in Zone 8. Though Uvalde, TX, is located in Zone 6, it appears to be less than 50 miles from Zone 8. Therefore, the submitted field trial data for bulb vegetables are adequate to fulfill data requirements.

The submitted field trial data are adequate to support the proposed soil directed use and reflect the use of a single in-furrow application of Admire Pro 550 SC, formulated as a SC containing 550 g ai/L. Following a single in-furrow spray application of imidacloprid at a target application rate of 0.5 lb ai/A (1x the proposed application rate), imidacloprid residues ranged from less than the limit of quantitation (LOQ; 0.020 ppm) to 1.50 ppm in/on green onions (PHIs of 136 to 193 days) and from <LOQ (0.05ppm) to 0.08 ppm in/on dry bulb onions (PHIs of 86 to 225 days). Although applications were made as an in-furrow spray application, HED expects the total residue of imidacloprid to be higher following a soil application than following a seed-treatment application. Therefore, the data are also adequate to support the proposed seed-treatment use. As residues on dry bulb onions and green onion varied by greater than 5X, a crop group tolerance is not appropriate. Therefore, using the maximum-likelihood estimation (MLE) procedures followed by NAFTA Maximum Residue Limit (MRL)/Tolerance Harmonization Workgroup methodology for green onions and dry bulb onions, the available crop field trial data indicate that the appropriate tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent are 0.15 ppm for onion, dry bulb, subgroup 3-07A; and 2.5 ppm for onion, green, subgroup 3-07B (see Section 860.1550 Proposed Tolerances). **A revised Section F should be submitted.**

No new crop field trial data were submitted in support of the tolerance for cereal grains. There are existing tolerances for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in/on barley, grain; corn, field, grain; corn, pop, grain; corn, sweet, kernel plus cob with husks removed; millet, pearl, grain; millet, proso, grain; oats, grain; rye, grain; sorghum, grain; and wheat, grain all at 0.05 ppm. In addition, there is a tolerance for indirect or inadvertent combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent in/on grain, cereal, group 15, also at 0.05 ppm. As there are identical seed-treatment uses with tolerances for most of the cereal grain crop group and a tolerance for indirect or inadvertent residues on the cereal grain crop group, the available residue data support the proposed tolerance for cereal grains. However, as there is no existing tolerance on rice grain, a tolerance for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent in/on grain, cereal, except rice, group 15 is appropriate. **A revised Section F should be submitted.**

For the remaining seed-treatment uses, the previously submitted and reviewed crop field trial data are adequate to support the proposed seed-treatment uses on vegetable, root, except sugar beet, subgroup 01B; vegetable, tuberous and corm, subgroup 01C; vegetable, leafy, except *Brassica*, subgroup 04A; vegetable, *Brassica*, group 5; vegetable, fruiting, group 8; and vegetable, cucurbit, group 9. Although applications were made using foliar and/or soil applications, HED expects the total residue of imidacloprid to be higher following a foliar or soil application than following a seed-treatment application. The currently established tolerances on these RACs are adequate.

No new processing study has been submitted in support of this action. There are no processed food and feed commodities associated with the proposed new seed-treatment use of imidacloprid on bulb vegetables. There are several processed food and feed commodities associated with the other commodities. However, as the established tolerances are adequate to support the proposed seed-treatment uses, a reevaluation of established processed food and feed tolerances or the need for additional tolerances are not necessary.

No new rotational crop studies were submitted in support of this action. The nature of the imidacloprid residue in rotational crops has been adequately characterized and identified. The identified residue in rotational crops is nearly identical to that identified in the primary crops, and the regulable residues in rotated crops are imidacloprid and its metabolites containing the 6-chloropyridinyl moiety. According to the current guidance, all the crops associated with this action are considered to be rotated. Adequate rotational crop data have been submitted and reviewed by HED (Memo, F. Griffith 8/9/94; PP#3F04169). The data were used to establish the current rotational crop tolerances under 40 CFR §180.472(d) for indirect and inadvertent residues of imidacloprid (Memo, G. Kramer, 9/23/96; D228500). The proposed labels specify rotational crop restrictions as follows: 1) 0 days for cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (crop group 15 except rice), canola, root vegetables (crop group 1), bulb vegetables (crop group 3), leafy green vegetables (crop group 4A), *Brassica* (cole) leafy vegetables (crop group 5), fruiting vegetables (crop group 8), and cucurbit vegetables (crop group 9); 2) 30 days for soybeans, dried beans, and dried peas; and 3) 12 months for all other crops. The rotational crop restrictions are adequate and are supported by available rotational crop data.

The International Residue Limit Status (IRLS) Sheet is attached as Attachment 3. There are no established Mexican MRLs for the proposed new uses. There are established Codex MRLs for the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety expressed as imidacloprid, in/on cereal grain at 0.05 ppm, leeks at 0.05 ppm, and bulb onions at 0.1 ppm. There are also established Canadian MRLs for 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-1*H*-imidazol-2-amine, including metabolites containing the 6-chloropicolyl moiety in/on sweet corn at 0.05 ppm and field corn at 0.05 ppm. With the exception of onions, there is no harmonization issue for these petitions. The Codex MRLs for leeks (0.05 ppm) and bulb onions (0.1 ppm) can not be harmonized as the U.S. use pattern necessitates higher tolerances (0.15 ppm for onion, dry bulb, subgroup 3-07A; and 2.5 ppm for onion, green, subgroup 3-07B).

5.2 Drinking Water Residue Profile

In a meeting on 12/18/02, the HED Metabolism Assessment Review Committee MARC recommended that for surface water risk assessment, degradates of concern should be parent and the three degradates: imidacloprid urea, imidacloprid guanidine, and imidacloprid olefin (Memo, J. Tyler, 1/13/03; D28740). EFED provided Tier 1 EDWCs for surface water (using FIRST) and groundwater (using SCI-GROW) for imidacloprid and its degradates (imidacloprid urea, imidacloprid guanidine, and imidacloprid olefin) (see Table 5.2.1). The EDWCs for imidacloprid were calculated based on a maximum application rate of 0.5 lb ai/A/season. The acute and chronic EDWCs in surface water are 36.0 ppb and 17.2 ppb of imidacloprid, based on applications of the chemical to citrus. The SCI-GROW generated EDWC is 2.09 ppb of imidacloprid.

Drinking Water Source (Model Used)	Use (rate modeled)	Maximum EDWC (ppb)	
		Acute and chronic	
Groundwater (SCI-GROW)	Citrus (0.5 lb ai/A)	Acute and chronic	2.09
Surface water (FIRST)	Citrus (0.5 lb ai/A)	Acute	36.0
	Citrus (0.5 lb ai/A)	Chronic	17.2

5.3 Dietary Exposure and Risk

Population Subgroup	Acute Dietary ¹ (95 th Percentile)		Chronic Dietary ²	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.038776	28	0.006091	11
All Infants (< 1 year old)	0.078739	56	0.011417	20
Children 1-2 years old	0.097752	70	0.018401	33
Children 3-5 years old	0.072662	52	0.013115	23
Children 6-12 years old	0.046055	33	0.007811	14
Youth 13-19 years old	0.029248	21	0.004618	8
Adults 20-49 years old	0.026424	19	0.004802	8
Adults 50+ years old	0.025515	18	0.005121	9
Females 13-49 years old	0.026266	19	0.004659	8

1. Acute dietary endpoint of 0.14 mg/kg/day applies to the general U.S. population and all population subgroups.

2. Chronic dietary endpoint of 0.057 mg/kg/day applies to the general U.S. population and all population subgroups.

5.3.1 Acute Dietary Exposure Results and Characterization

An unrefined, acute dietary exposure assessment using tolerance-level residues and assuming 100% CT for all registered and proposed commodities was conducted for the general U.S. population and various population subgroups. Exposure to drinking water was incorporated

directly in the dietary assessment using the acute (peak) concentration for surface water generated by the FIRST model, 36.0 ppb. This assessment indicates that the acute dietary exposure estimates are below HED's level of concern, <100% of the aPAD, at the 95th exposure percentile for the general U.S. population and all other population subgroups. The acute dietary exposure is estimated for the U.S. population at 28% of the aPAD and the most highly exposed population subgroup, children 1-2 years old, at 70% of the aPAD.

5.3.2 Chronic Dietary Exposure Results and Characterization

A partially refined, chronic dietary exposure assessment (using tolerance-level residues for all registered and proposed commodities, and %CT information for some commodities) was conducted for the general U.S. population and various population subgroups. Exposure to drinking water was incorporated directly into the dietary assessment using the chronic (annual average) concentration for surface water generated by the FIRST model, 17.2 ppb. This assessment concludes that the chronic dietary exposure estimates are below HED's level of concern (<100% cPAD) for the general U.S. population and all population subgroups. The chronic dietary exposure is estimated for the U.S. population at 11% of the cPAD and the most highly exposed population subgroup, children 1-2 years old, at 32% of the cPAD.

5.3.3 Anticipated Residue and Percent Crop Treated Information

No anticipated residue information was used in the dietary exposure assessments. The %CT information used in the chronic assessment is presented in Table 5.3.3.1.

Commodity	Avg. Percent Crop Treated Data
Almonds	<1
Apples	25
Artichokes	5
Avocados	<1
Blueberries	10
Broccoli	50
Cabbage	20
Cantaloupe	40
Cauliflower	50
Celery	10
Cherries	10
Collards	Not provided
Cotton	10
Cucumbers	5
Eggplant	35
Field corn	<2.5
Filberts (hazelnuts)	<1
Grapefruit	10
Grapes	30
Honeydew	30
Lemons	5
Lettuce	65
Oranges	10
Peaches	5
Pears	5
Pecans	10
Peppers	30
Potatoes	35
Prunes	<1

Table 5.3.3.1. Screening Level Estimates of Agricultural Uses of Imidacloprid Used in Chronic Dietary Exposure Assessment¹.

Commodity	Avg. Percent Crop Treated Data
Pumpkin	10
Soybeans	<1
Spinach	20
Squash	10
Strawberries	10
Sugar beets	<1
Sweet corn	<1
Tangerines	5
Tobacco	20
Tomatoes	15
Walnuts	<1
Watermelon	15

6.0 Residential (Non-Occupational) Exposure/Risk Characterization

Imidacloprid is currently registered for use on residential lawns and turf (including golf courses), ornamental plantings, pets, and indoor and outdoor residential sites, including pre-and post construction termiticide and wood preservative. A residential exposure assessment for these uses was included in the most recent human-health risk assessment (Memo, J. Tyler *et al.*, 6/30/09; D365445). None of the residential handler and post-application exposure scenarios for these uses had risks of concern (i.e., MOEs >100).

In this action, new residential uses are proposed on mattresses for bed-bug control. Also, use of imidacloprid as a crack and crevice treatment is included in this document as these residential uses have not been previously evaluated by HED and the registered spot-on pet use has been reassessed due to more recent chemical-specific data that was submitted to the Agency.

According to the proposed product label for Temprid™ SC Insecticide, the use of this product is intended for pest management professionals and commercial use only; however, the product is not a RUP and could potentially be used by homeowners. Therefore, both residential handler and post-application assessments for these uses have been conducted.

In this section, short- and intermediate-term residential handler and post-application risks were assessed. Long-term residential exposure is not expected for imidacloprid. Short- and intermediate-term estimates of exposure and risk for residents who treat their homes (handlers) result in MOEs that are greater than 100 and therefore, not of concern. HED also assessed short- and intermediate-term potential post-application exposure based on use of imidacloprid on mattresses for bed bug control and as an indoor crack and crevice treatment. For the bed-bug use, dermal post-application risk is not of concern (i.e., MOEs >100) for both adults and toddlers. For the crack and crevice use, dermal, inhalation and incidental oral (toddlers only) risk estimates are not of concern (i.e., MOEs >100) for both adults and toddlers. Even when exposures from the bed-bug use and the crack and crevice use were combined, risk estimates for adults and toddlers were not of concern (i.e., MOEs >100). The combined residential exposure for the bed-bug and crack and crevice treatment uses is higher than that for other residential uses of imidacloprid; therefore, these exposures were combined with dietary and drinking water exposure in aggregate risk assessments (Section 7).

6.1 Residential Handler Exposure

Residential handler exposure is expected for handlers that treat mattresses (and bed frames) for bed-bug control as well as indoor surfaces (crack and crevice uses). HED assessed short- and intermediate-term exposure and risk for these uses.

According to the proposed product label for Temprid™ SC Insecticide, the use of this product is intended for pest management professionals and commercial use only; however, the product is not a RUP and could potentially be used by homeowners. Therefore, a residential handler assessment for these uses has been conducted.

For the residential crack and crevice and bed-bug uses, applications will be made using a low-pressure handwand. HED expects that a larger area will be sprayed when handlers treat for the crack and crevice uses (baseboards and other indoor surfaces are sprayed) compared to that for the bed-bug uses (mattresses and bed frame). Therefore, HED assessed risk to residential handlers based on the crack and crevice use pattern, assuming ½ gallon of spray is used per day.

Based upon the proposed use pattern, HED expects the following residential pesticide handler scenario:

- Mixing/loading/applying sprays with low-pressure handwand (PHED).

HED expects the duration of exposure for residential uses to be short- (1-30 days) and/or intermediate-term (1-6 months) in duration. These estimates are presented in Table 6.1.1 below.

Assessing exposures and risks resulting from residential uses is very similar to assessing occupational exposures and risks, except that a tiered approach for personal protection using increasing levels of PPE is not used in residential handler risk assessments. Homeowner handler assessments are based on the assumption that individuals are wearing shorts, short-sleeved shirts, socks, and shoes.

No chemical-specific data were available with which to assess potential exposure to residential pesticide handlers. The estimates of exposure to pesticide handlers are based upon surrogate study data available in the PHED (v. 1.1, 1998). Table 6.1.1 provides estimates of exposure and risk for residential handlers. Risk estimates for residential handlers are not of concern (MOEs>100).

Table 6.1.1. Residential Handler Exposure and Risk for Crack and Crevice Use.									
Application Rate (lb ai/gallon) ^a	Amount Handled (gallons) ^b	Unit Exposure (mg/lb ai) ^c		Dose (mg/kg/day) ^{e,f}			MOE ^{g,h}		
		Baseline Dermal ^d	Baseline Inhalation ^d	Baseline Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Baseline Dermal	Baseline Inhalation	Baseline Dermal + Baseline Inhalation
SHORT-TERM									
Mixing/Loading/Applying Wettable Powders with Low-Pressure Handwand (PHED)									
0.008	0.5	250	1.063	0.001	0.000061	0.0011	9,700	160,000	9,200

Table 6.1.1. Residential Handler Exposure and Risk for Crack and Crevice Use.

Application Rate (lb ai/gallon) ^a	Amount Handled (gallons) ^b	Unit Exposure (mg/lb ai) ^c		Dose (mg/kg/day) ^{e,f}			MOE ^{g,h}		
		Baseline Dermal ^d	Baseline Inhalation ^d	Baseline Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Baseline Dermal	Baseline Inhalation	Baseline Dermal + Baseline Inhalation
INTERMEDIATE-TERM Mixing/Loading/Applying Wettable Powders with Low-Pressure Handwand (PHED)									
0.008	0.5	250	1.063	0.001	0.000061	0.0011	9,000	150,000	8,500

- a. Application Rates based on proposed use on label for imidacloprid product Temprid™ SC Insecticide (Reg. No. 432-1483)
- b. ExpoSAC Policy #12.
- c. Unit Exposures based on PHED Version 1.1.
- d. Baseline Dermal: Short-sleeve shirt, shorts, and no gloves; Baseline Inhalation: no respirator.
- e. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) * application rate (lb ai/gallon) * amount handled (gallons) * dermal absorption factor (7.2%) / body weight (70 kg).
- f. Inhalation Dose (mg/kg/day) = daily unit exposure (mg/lb ai) * application rate (lb ai/gallon) * amount handled (gallons) * inhalation absorption (100%) / body weight (70 kg).
- g. MOE = NOAEL (short-term = 10 mg/kg/day; intermediate-term = 9.3 mg/kg/day) / daily dose (mg/kg/day). Level of concern = 100.
- h. Baseline Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).

In a previous risk assessment (Memo, J. Tyler *et al.*, 6/30/09; D365445), HED included a residential handler assessment for the registered outdoor and pet uses. Since that assessment, a more recent chemical-specific study (MRID 465941-03) has been submitted to the Agency for the spot-on pet product. HED has reviewed this study and deemed it acceptable for use in exposure and risk assessment (D320041). The data from this study supersedes the data from the older study used in the previous assessment. HED does not believe that using this postapplication data to assess residential handler exposure would be appropriate since it is believed that handler exposure is negligible following the use of spot-on products. Therefore, only postapplication exposure from the use of the spot-on pet product has been included here.

Table 6.1.2 is a summary of the previously assessed residential handler use patterns and corresponding MOEs. All MOEs were >100; and therefore, were not of concern.

Table 6.1.2. Summary of Previously Assessed Short-term Residential Handler Exposures and Risks.

Scenarios Assessed	DP#	Application Rate	Area Treated/ Amount Applied (per day)	Unit Exposure (mg/lb ai handled)		Dose (mg/kg/day)		MOE ^a	
				Inhalation	Dermal	Inhalation	Dermal	Inhalation	Dermal
Granular/ push-type spreader application	281610	0.4 lb ai/A	0.5 A	0.00091	0.68	0.0000026	0.000136	72,000	
0.000139									
Ready-to-use trigger pump spray		Negligible, see hose-end spray							
Potted plant spikes		10 two gram spikes or 0.0011 lb ai	10 plants	Negligible	356	Negligible	0.00392	Negligible	2600
Plant potting medium		0.00288	1 container	Negligible	3560	Negligible	0.01	Negligible	1000

Scenarios Assessed	DP#	Application Rate	Area Treated/ Amount Applied (per day)	Unit Exposure (mg/lb ai handled)		Dose (mg/kg/day)		MOE ^a	
				Inhalation	Dermal	Inhalation	Dermal	Inhalation	Dermal
Garden hose-end spray		0.0002196 lb ai/1000 ft ²	22,000 ft ²	11.0	0.016	0.000053	0.0000011	185,000	
Soil drench bucket/ water can		0.245 lb ai/day	20 medium trees or 42 average-size shrubs	0.0012	2.9	0.0000042	0.0007	14,000	

a. MOE = NOAEL/Dose where short-term NOAEL is 10 mg/kg/day.

6.2 Residential Post-Application Exposure

HED has determined that there is potential for post-application exposure to adults and children/toddlers from the many residential uses of imidacloprid. Indoor uses result in the most significant potential for post-application exposure. HED has evaluated all significant sources of post-application exposure for populations of concern and presented them below.

Post-application inhalation, dermal and incidental oral exposures (children only) are possible from the proposed and registered residential uses of imidacloprid. Short- and intermediate-term residential post-application exposures are likely for adults and children. It is not expected that any of the proposed or registered residential uses would result in exposures longer than 6 months; therefore, long-term risks are not assessed. Imidacloprid is registered for use as a pre- and post-construction termiticide; however, due to the low volatility coupled with the fact that it is used pre- and post-construction only, HED does not expect there to be potential for long-term exposure to imidacloprid from this use.

Dermal exposures have been estimated using Day-0 residue values which is considered a conservative assumption for longer-term exposures since residue values would be expected to dissipate over time.

All non-dietary sources of post-application exposure were combined to obtain an estimate of potential combined exposure that could be used for the aggregate assessment. Combined residential exposure from the indoor crack and crevice use and the bed-bug/mattress use consists of the highest adult dermal and inhalation exposures as well as the highest toddler dermal, inhalation and oral (hand-to-mouth) exposures compared to other residential uses. All combined post-application scenarios resulted in MOEs greater than 100 and were not of concern to HED. Table 6.3.1 provides a summary of the combined residential indoor crack and crevice and bed-bug mattress exposures and risks.

Post-application Inhalation

Post-application inhalation exposure can result from the registered crack and crevice use, as well as the proposed bed-bug/mattress use. The saturation concentration in air for imidacloprid was

calculated and used as a screening-level air concentration for the post-application inhalation assessment.

Exposure was estimated for individuals spending time in areas sprayed with imidacloprid during the initial 16 hours of time following treatment. Exposure and risk were estimated for short- and intermediate-term time durations for both adults and toddlers. Other conservative assumptions were built into the inhalation exposure assessment (see memo, K. Lowe, D367396, 11/10/09).

All post-application inhalation scenarios resulted in MOEs greater than 100 and are not of concern to HED. Table 6.2.1 summarizes the post-application inhalation exposure and risk from the indoor uses of imidacloprid.

Population	C_{sat} (mg/m ³) ^a	IR (m ³ /hr)	ET (hr)	Inhalation Dose (mg/kg/day) ^b	Inhalation MOE ^c	
					Short-term	Intermediate-term
Adult	0.0014	0.55	16	0.00017	57,000	53,000
Toddler		0.36	16	0.00053	19,000	17,000

- a. $C_{sat} = [\text{Vapor pressure (1 X 10}^{-7} \text{ mmHg)} * \text{Conversion factor (atm/760 mm Hg)} * \text{Molecular Weight (g/mol)} * \text{Conversion factor (10}^3 \text{ mg/g)} * \text{Conversion factor (10}^3 \text{ L/m}^3)] / [\text{R (Gas constant = 0.0821 L-atm/mol-K)} * \text{Temperature (296 K)}]$.
- b. $\text{Inhalation Dose (mg/kg/day)} = C_{sat} * \text{Inhalation Rate (m}^3\text{/hr)} * \text{Exposure Time (hr)} / \text{Body Weight (kg)}$.
- c. $\text{Inhalation MOE} = \text{NOAEL (Short-term = 10 mg/kg/day and Intermediate-term = 9.3 mg/kg/day)} / \text{Dose (mg/kg/day)}$.

Post-application Dermal

Post-application dermal exposure can result from pesticide residue transfer to the skin of individuals who contact previously treated indoor surfaces (e.g., carpets, floors, furniture, and other surfaces) during standard activities. Such exposure is assumed to occur for adults and toddlers. An assessment has been conducted for both dermal exposures from the registered crack and crevice use, as well as the proposed bed-bug use (mattress application).

For the bed-bug use, applications are allowed for both mattresses and furniture (tufts, seams, folds, and edges); however, this assessment covers exposure from applications to mattresses only. The assessment for the mattress application is based on an assumption regarding the amount of product applied per area (i.e., a twin-size bed). It is assumed that the surface area of a standard size couch would be similar to that of a twin-size bed, and that the exposure time for dermal contact with furniture would be less than that for a bed. In addition, the product label includes a statement which indicates that the product should not be applied to furniture or upholstery where prolonged contact with humans will occur. For these reasons, an assessment for exposure to treated furniture was not included in this document and the assessment for treatment of a mattress is considered worst-case and protective of treatment of furniture.

Crack and Crevice Use

The following key assumptions were used in the dermal post-application exposure assessment for the crack and crevice use:

- Deposited residue: based on default residue value of 12 ug/cm² for a 0.5% spray [HED]

Draft SOPs for Residential Exposure Assessments, 2000]. For the current product, applications are to be made with 0.15% or 0.075% sprays (for both active ingredients; 0.1% and 0.05% imidacloprid). Therefore, the residue value for imidacloprid from the crack and crevice use is 2.4 ug/cm² for the 0.15% spray and 1.2 ug/cm² for the 0.075% spray.

- Fraction of ai available for transfer: 0.05 for carpet and 0.1 for hard surfaces
- Transfer coefficient: 16,700 cm²/hr for adults and 6,000 cm²/hr for children
- Exposure time: 8 hours/day for carpet and 4 hours/day for hard surfaces
- Individuals contact previously treated carpets or hard surfaces on the same day a pesticide is applied.

All post-application dermal scenarios for the crack and crevice use resulted in MOEs greater than 100 and are not of concern to HED. Table 6.2.2 summarizes the dermal exposure and risk from the crack and crevice use.

Surface Type	Population	Percent spray applied ^a	Surface Residue ^b (ug/cm ²)	Fraction transferred	Transfer Coefficient (cm ² /hr)	Exposure time (hr/day)	Dermal Dose (mg/kg/day)	Dermal MOE	
								S-T	I-T
Carpet	Adult	0.15%	2.400	0.05	16,700	8	0.016	610	560
	Toddler				6,000		0.028	360	340
	Adult	0.075%	1.200		16,700		0.0082	1,200	1,100
	Toddler				6,000		0.014	720	670
Hard Surfaces	Adult	0.15%	2.400	0.10	16,700	4	0.016	610	560
	Toddler				6,000		0.028	360	340
	Adult	0.075%	1.200		16,700		0.0082	1,200	1,100
	Toddler				6,000		0.014	720	670

- a. Percent spray applied is considering both active ingredients. For imidacloprid alone, the percent spray applied is 0.1% and 0.05%.
- b. Surface residue = (12 ug/cm² * 0.1% spray) / (0.5% spray) = 2.4 ug/cm² and (12 ug/cm² * 0.05% spray) / (0.5% spray) = 1.2 ug/cm²
- c. Dose (mg/kg/day) = Surface residue (ug/cm²) * Fraction transferred * Transfer coefficient (cm²/hr) * Exposure time (hr/day) * Conversion factor (0.001 mg/ug) * Dermal Absorption Factor (7.2%) / Body Weight (70 kg for adults and 15 kg for toddlers).
- d. MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day), where short-term (S-T) dermal NOAEL = 10 mg/kg/day and intermediate-term (I-T) = 9.3 mg/kg/day.

Bed-Bug Use – Mattress Application

In order to assess the dermal post-application exposure from the proposed bed-bug use, HED used the best available data and made several conservative assumptions (see: memo, K. Lowe, D367396, 11/23/09).

All post-application dermal scenarios for the bed-bug use on mattresses resulted in MOEs greater than 100 and are not of concern to HED. Table 6.2.3 summarizes the dermal exposure and risk from the bed-bug use on mattresses.

Surface Type	Population	Residue (ug/cm ²) ^a	Surface area /	Fraction of skin in	Transfer Efficiency	Protection factor	Dermal Dose (mg/kg/day) ^b	Dermal MOE
--------------	------------	--	----------------	---------------------	---------------------	-------------------	--------------------------------------	------------

			Body Weight Ratio (cm ² /kg)	contact with surface				S-T	I-T
Mattress	Adult	2.07	290	0.5	0.05	0.5	0.00054	19,000	17,000
	Toddler		620				0.0012	8,700	8,100

- a. Residue value determined based on application rate (0.075% spray; 0.004 lb ai/gal) and assumptions for area treated and amount applied (see above text).
- b. Dermal dose (mg/kg/day) = Surface residue (ug/cm²) * Surface area / Body weight Ratio (cm²/kg) * Fraction of body that contacts residue (0.5) * Conversion factor (0.001 mg/ug) * Transfer efficiency (0.05) * Protection factor (0.5) * Dermal Absorption Factor (7.2%).
- c. MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day), where short-term (S-T) dermal NOAEL = 10 mg/kg/day and intermediate-term (I-T) = 9.3 mg/kg/day.

Post-application Incidental Oral

Post-application incidental oral exposure resulting from hand-to-mouth activity can occur as a result of the indoor crack and crevice use and the bed-bug/mattress use. Only incidental oral exposures resulting from the crack and crevice use have been assessed here since they are considered to be protective of the mattress application for the following reasons: (1) a lower application rate is allowed for the mattress application compared to the crack and crevice application, (2) a protection factor of 0.5 is assumed for the mattress exposures due to the presence of a bed sheet over the mattress, and (3) hand-to-mouth activity is assumed to be reduced while the child is sleeping.

The hand-to-mouth exposure scenario was assessed using the HED Draft SOPs for Residential Exposure Assessments (2000), and the Revisions to the SOPs for Residential Exposure Assessment (ExpoSAC Policy #12). This scenario assumes pesticide residues are transferred to the skin of children during post-application contact with treated indoor areas and are subsequently ingested as a result of hand-to-mouth transfer.

MOEs for the hand-to-mouth post-application exposure assessment are all greater than 100 for all scenarios and are not of concern to HED. Table 6.2.4 summarizes the MOEs for hand-to-mouth transfer of pesticide residues from the indoor crack and crevice use of imidacloprid.

Table 6.2.4. Post-application Incidental Oral (Hand-to-Mouth) Exposure for Children for Crack and Crevice Use.

Percent spray applied ^a	Fraction transferred	Surface area of the hand (cm ² /event)	Exposure Frequency (events/hr)		Saliva Extraction Factor	Exposure Time (hrs/day)	Surface Residue (ug/cm ²) ^b	Oral Dose (mg/kg/day) ^c		Incidental Oral MOE ^d	
			S-T	I-T				S-T	I-T	S-T	I-T
Carpets											
0.15% spray	0.05	20	20	9.5	50%	8	2.40	0.0128	0.0061	780	1,500
0.075% spray							1.20	0.0064	0.0030	1,600	3,100

Table 6.2.4. Post-application Incidental Oral (Hand-to-Mouth) Exposure for Children for Crack and Crevice Use.

Percent spray applied ^a	Fraction transferred	Surface area of the hand (cm ² /event)	Exposure Frequency (events/hr)		Saliva Extraction Factor	Exposure Time (hrs/day)	Surface Residue (ug/cm ²) ^b	Oral Dose (mg/kg/day) ^c		Incidental Oral MOE ^d	
			S-T	I-T				S-T	I-T	S-T	I-T
Hard Surfaces											
0.15% spray	0.10	20	20	9.5	50%	4	2.40	0.0128	0.0061	780	1,500
0.075% spray							1.20	0.0064	0.0030	1,600	3,100

- a. Percent spray applied is considering both active ingredients. For imidacloprid alone, the percent spray applied is 0.1% and 0.05%.
- b. Surface residue = (12 ug/cm² * 0.1% spray) / (0.5% spray) = 2.4 ug/cm² and (12 ug/cm² * 0.05% spray) / (0.5% spray) = 1.2 ug/cm²
- c. Dose (mg/kg/day) = Surface residue (ug/cm²) * Fraction transferred * Surface area of hands (cm²/event) * Exposure frequency (events/hr) * Exposure time (hr/day) x Saliva extraction factor x Conversion factor (0.001 mg/ug) / Body Weight (15 kg for toddlers).
- d. MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day), where short-term (S-T) incidental oral NOAEL = 10 mg/kg/day and intermediate-term (I-T) = 9.3 mg/kg/day.

In a previous risk assessment (Memo, J. Tyler *et al.*, 6/30/09; D365445), HED included a post-application assessment for the registered outdoor and pet uses. Since that assessment, a more recent chemical-specific study (MRID 465941-03) has been submitted to the Agency for the spot-on pet product. HED has reviewed this study and deemed it acceptable for use in exposure and risk assessment (D320041). Therefore, HED has revised the postapplication dermal and incidental oral exposure assessment for the pet use based on the available data. A summary of the study and revisions is provided below.

MRID 465941-03, Stroking Test in Dogs After Topical Application of Imidacloprid 10% (w/v) + Permethrin 50% (w/v) Spot-On.

Data from this study was used to assess dermal and incidental oral exposure to imidacloprid following its use as a dog spot-on treatment. The study measured the dislodgeability of the test substance from the haircoats of dogs treated with a spot-on formulation containing imidacloprid and permethrin as the active ingredients. The test substance was administered to Beagle dogs by topical application to the back (spine) using pipettes intended for commercial application. The test substance (2.5 ml) was applied in 4 single spots. Residues were collected to assess the postapplication exposure from treated dogs by stroking the dogs three times from head to tail over the application spots, while wearing cotton gloves. Medium pressure was used to stroke the dogs. Samples were collected at each of the following sampling intervals: 30 minutes, 2 hours, 12 hours, and 24 hours after application. A separate glove was used for each of five animals tested.

The study reported the amounts of imidacloprid and permethrin per glove for each animal in each group at each sampling period. Means, standard deviations, relative standard deviations, minimums and maximums were also reported. When residues were less than the limit of quantitation (LOQ), ½ LOQ in the calculations. For imidacloprid, average residues were 0.543 ± 0.569 mg/glove at 30 minutes after treatment, less than the LOQ at 2 hours after treatment, 0.715 ± 0.375 mg/glove at 12 hours after treatment, and 1.14 ± 0.487 mg/glove at 24 hours after treatment. Imidacloprid residues were less than the LOQ in one of the five replicates at the 30 minute interval, three of the five replicates at the 2 hour interval, and in one of the five replicates at the 12 hour interval. The current registered product for imidacloprid (Advantage[®] 110 EPA Reg. No 11556-121) allows for a maximum of 5 mL to be applied to a dog. After an application of 2.5 mL in the study, the maximum imidacloprid residue found on the study subjects' cotton

glove was 1.14 mg at 24 hours. This value was adjusted for the maximum application volume allowed by the label and used in the postapplication exposure assessment (i.e., 2.28 mg).

The approach used to estimate dermal and oral exposures is believed to represent the high-end of toddler's potential exposures from spot-on treated dogs. Highly absorbent cotton gloves were used to collect the samples which may not reflect the actual absorption of human skin. However, no absorbency data were presented to quantify the difference between cotton gloves and bare hands, and residues in many of the cotton glove samples were less than the LOQ.

Exposures after contact with treated pets have been addressed using the latest HED approaches for this scenario including:

- a equilibrium approach based on a single "hug" of the treated animal is used to assess dermal exposure as described in the 1999 Agency SAP Overview document (i.e., the skin loads after a single contact with the treated animal and additional contacts don't proportionally add exposures), the surface area of the dermal hug is based on a skin surface area and typical clothing;
- risks are based on an even loading of residues across the entire surface of a 30 lb dog (chosen as a representative animal), the animal surface area was calculated using $(12.3 * \text{Body Weight (g)} 0.65)$ from HED's 1993 Wildlife Exposure Factors Handbook (i.e., dog surface area of 5986 cm²);
- for spot-on scenarios, data from MRID 465941-03 was used to assess dermal and incidental oral exposure to imidacloprid.

Dermal Exposure From Treated Pets:

The approach used to calculate dermal exposure from contacting treated pets is:

$$D = \{((AR * F_{AR}) / SA_{pet}) * (1 - DR)^t * SA_{hug} * DA\} / BW$$

Where:

ADD	=	average daily dose via dermal pet contact (mg/kg/day);
AR	=	application rate or amount applied to animal in a single treatment (mg ai/animal);
F _{AR}	=	fraction of the application rate available as transferable residue (20%);
SA _{pet}	=	surface area of a treated 30 lb dog (5,986 cm ² /animal);
t	=	time after application (days);
DR	=	fractional dissipation rate per day (5% per day);
SA _{hug}	=	surface area of a hug (cm ² contact/hug);
DA	=	dermal absorption factor; and
BW	=	body weight (kg).

Hand-to-mouth Transfer of Pesticide Residues From Treated Pets:

The approach used to calculate non-dietary exposures that are attributable to hand-to-mouth behavior on pets is:

$$D = \{((AR * F_{AR}) / SA_{pet}) * (1 - DR)^t * SE * SA_{hands} * FQ * DA\} / BW$$

where:

- D = nondietary ingestion dose from with treated pets (mg/day);
- AR = application rate or amount applied to animal in a single treatment (mg ai/animal);
- F_{AR} = fraction of the application rate available as transferable residue (20%);
- SA_{pet} = surface area of a treated dog (5,986 cm²/animal);
- t = time after application (days);
- DR = fractional dissipation rate per day (5% per day);
- SE = saliva extraction factor (50% extractability);
- SA_{hands} = surface area of the hands (20 cm²);
- FQ = frequency of hand-to-mouth activity (1 event/day);
- DA = dermal absorption factor; and
- BW = body weight (15 kg).

Table 6.2.5. Dermal postapplication exposure from treated pets

Exposure Scenario	Population	Transferable residue (mg ai)	Surface Area of 30 lb dog (cm ² /animal)	Surface Area of hug (cm ² contact/hug)	Dermal Dose (mg/kg/day)	Dermal MOE	
						Short-term	Intermediate-term
Spot-on	Toddler (3 to < 6 year olds)	2.28	5986	1,875	0.0033	3,000	2,800
Spot-on	Adult	2.28	5986	5,625	0.0021	4,700	4,300

Table 6.2.6. Incidental oral postapplication exposure for children (3 to <6 years) from treated pets -- Spot-on formulation

Transferable residue (mg ai)	Surface Area of 30 lb Dog (cm ² / animal)	Saliva Extraction Factor	Surface Area of Fingers (cm ²)	Event Frequency (events/ day)	Oral Dose (mg/kg/day)	Oral MOE	
						Short-term	Intermediate-term
2.28	5986	0.50	20	1	0.00025	39,000	37,000

Table 6.2.7 is a summary of the previously assessed residential post-application use patterns and corresponding MOEs. All MOEs were >100; and therefore, were not of concern.

Table 6.2.7. Summary of Previously Assessed^a Residential Post-Application Exposures and Risks.

Scenario	Activity	Dose (mg/kg/day)	MOE ^b
Turf	Adult dermal	0.00053	19,000
	Toddler dermal	0.001	10,000
	Toddler incidental oral -- hand to mouth	0.0059	1,700
	Toddler incidental oral -- ingestion of treated soil	0.00002	500,000
	Toddler incidental oral -- ingestion of granules	0.12	350
	Adult golfer	0.00016	62,500
	Child golfer	0.000272	37,000
Pet	Adult dermal	0.0021	ST = 4,700 IT = 4,300
	Toddler dermal	0.0033	ST = 3,000 IT = 2,800
	Toddler incidental oral -- hand to mouth	0.00025	ST = 39,000 IT = 37,000

- a. Residential postapplication exposures originally assessed in ORE memo D281610 and risk assessment memo D365445. The pet use has been reassessed in this memo based on best available data.
- b. MOE = NOAEL/Dose where short-term NOAEL is 10 mg/kg/day and intermediate-term NOAEL = 9.3 mg/kg/day.

6.3 Combined Residential Risk Estimates

HED combines risk values resulting from separate residential exposure scenarios when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population. Furthermore, for imidacloprid, since similar endpoints were selected for dermal, inhalation and oral exposures, risks from the three exposure routes may be combined. Therefore, all non-dietary sources of post-application exposure were combined to obtain an estimate of potential combined exposure which could be used for the aggregate assessment. Handler exposures were not combined with post-application exposures.

A combined residential assessment has been included here based on post-application exposure from the indoor crack and crevice use and the bed-bug/mattress use. Exposures from these scenarios have been combined since both are indoor scenarios and could potentially occur at the same time. These scenarios consist of adult dermal and inhalation post-application exposures as well as toddler dermal, inhalation and oral (hand-to-mouth) post-application exposures. All combined post-application scenarios resulted in MOEs greater than 100 and were not of concern to HED. Table 6.3.1 provides a summary of the combined residential indoor crack and crevice and bed-bug mattress exposures and risks. These values were used to assess aggregate exposure for imidacloprid (Tables 7.2 and 7.3).

Table 6.3.1. Combined Residential Exposure and Risk Estimates from the Indoor Crack and Crevice and Bed-Bug Mattress Use.				
Population	Post-application Scenarios	Daily Dose (mg/kg/day) ^a	MOE ^b	Combined MOE ^c
Short-term				
Adult	Dermal – crack and crevice	0.016	610	580
	Inhalation – crack and crevice	0.00017	57,000	
	Dermal - bed bug/mattress	0.00054	19,000	
Toddler	Dermal - crack and crevice	0.028	360	240
	Inhalation – crack and crevice	0.00019	19,000	
	Hand-to-Mouth – crack and crevice	0.0128	780	
	Dermal – bed bug/mattress	0.0012	8,700	
Intermediate-term				
Adult	Dermal – crack and crevice	0.016	560	540
	Inhalation – crack and crevice	0.00017	53,000	
	Dermal - bed bug mattress	0.00054	17,000	
Toddler	Dermal - indoor crack and crevice	0.028	340	260

Table 6.3.1. Combined Residential Exposure and Risk Estimates from the Indoor Crack and Crevice and Bed-Bug Mattress Use.

Population	Post-application Scenarios	Daily Dose (mg/kg/day) ^a	MOE ^b	Combined MOE ^c
	Inhalation – crack and crevice	0.00019	17,000	
	Hand-to-Mouth – crack and crevice	0.0061	1,500	
	Dermal – bed bug/mattress	0.0012	8,100	

a. Daily Dose = see Tables 4.2.1, 4.2.2, 4.2.3, and 4.2.4.

b. MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where S-T NOAEL = 10 mg/kg/day and I-T NOAEL = 9.3 mg/kg/day

c. Adult Combined MOE = $1 / [(1/\text{MOE}_{\text{Dermal - crack and crevice}}) + (1/\text{MOE}_{\text{Dermal - bed bug mattress}}) + (1/\text{MOE}_{\text{Inhalation}})]$.

Toddler Combined MOE = $1 / [(1/\text{MOE}_{\text{Dermal - crack and crevice}}) + (1/\text{MOE}_{\text{Dermal - bed bug mattress}}) + (1/\text{MOE}_{\text{Inhalation}})] + (1/\text{MOE}_{\text{Hand-to-Mouth}})]$.

In the previous 2009 imidacloprid residential assessment (Memo, J. Tyler *et al.*, 6/30/09; D365445), a combined residential assessment was performed for the registered turf and pet uses. Exposures were lower than those estimated for crack and crevice and bed-bug uses and there were no risks of concern (see Table 6.3.2).

Table 6.3.2. Summary of Previously Assessed^a Child Combined Risk Estimates.

Exposure Scenario		Dose mg/kg/day	MOE	Combined Dose mg/kg/day	COMBINED MOE ^b
Toddler - Treated Turf	Oral hand-to-mouth post-application exposure from contacting treated turf	0.0059	1,700	0.00692	1,500
	Incidental oral post-application exposure from ingestion of treated soil	0.00002	500,000		
	Dermal post-application exposure from contacting turf	0.001	10,000		
Toddler - Treated Pet	Incidental oral post-application exposure from contacting treated pet	0.00025	ST = 39,000 IT = 37,000	0.00355	ST = 2,800 IT = 2,600
	Dermal post-application exposure from pet "hug"/ contacting treated pet	0.0033	ST = 3,000 IT = 2,800		

a. Residential combined exposures originally assessed in ORE memo D281610 and risk assessment memo D365445. The pet use has been reassessed in this memo based on best available data.

b. Combined MOEs are presented for toddler oral + dermal exposure to treated turf, and oral + dermal exposure to a treated pet. Combined MOEs are expressed as: $\text{MOE}_{\text{DERMAL}} + \text{MOE}_{\text{ORAL}}$. Combined MOEs are presented for an adult who applies the material to his/her lawn and then experiences post-application exposure.

6.3 Other (Spray Drift, etc.)

Spray drift is often a potential source of exposure to residents nearby to agricultural spraying operations. This is particularly the case with aerial operations, but to a lesser extent, could also be a potential source of exposure from ground application methods. As indicated in this assessment, imidacloprid can be directly applied to residential turf. The rates of application to residential turf are generally equal to or greater than the agricultural rates of application. The resulting MOEs are not of concern to HED. Therefore, based on this assessment, HED believes that it is unlikely that there is higher potential for risk of exposure to spray drift from agricultural uses of this chemical than have been assessed for direct residential applications.

7.0 Aggregate Risk Assessments and Risk Characterization

In accordance with the FQPA, HED must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure. In the case of imidacloprid, aggregate risk assessments were performed for acute aggregate exposure (food + drinking water), short-term aggregate exposure (food + drinking water + residential), intermediate-term aggregate exposure (food + drinking water + residential) and chronic aggregate exposure (food + drinking water). Long-term residential exposure is not expected based on the registered and proposed use patterns. A cancer aggregate risk assessment was not performed because imidacloprid is not carcinogenic. All potential exposure pathways were assessed in the aggregate risk assessment.

7.1 Acute Aggregate Risk

The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of imidacloprid (food and drinking water). The dermal, inhalation, and incidental oral exposures resulting from short-term residential applications are assessed separately. The acute dietary exposure estimates are below HED's level of concern (<100% aPAD) at the 95th exposure percentile for the general U.S. population (28% of the aPAD) and all other population subgroups (see Table 5.3.1). The most highly-exposed population subgroup is children 1-2 years old, at 70% of the aPAD. Therefore, the acute aggregate risk associated with the proposed use of imidacloprid does not exceed HED's level of concern for the general U.S. population or any population subgroups.

7.2 Short-Term Aggregate Risk

The short-term aggregate risk assessment estimates risks likely to result from 1- to 30-day exposures to imidacloprid residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used and average values are used for food and drinking water exposures.

Short-term aggregate risk assessments are necessary for both adults and children as there is potential for both short-term dermal and inhalation handler exposure, and short-term post-application exposure from the residential uses of imidacloprid. For the short-term aggregate risk assessment, potential residential post-application exposures were combined with food and drinking water exposures. Toddlers' residential short-term aggregate exposure includes dermal and inhalation exposure from the crack and crevice uses, dermal exposure from the bed-bug uses, and incidental oral exposure from hand-to-mouth contact with treated surfaces. Adult short-term aggregate exposure includes dermal and inhalation exposure from indoor crack and crevice uses, and dermal exposure from the bed-bug uses. See Table 6.3.1 for more information on combined exposures.

The combined short-term exposure from residential crack and crevice and bed-bug treatment resulted in the highest exposure for adults (exposure = 0.017 mg/kg/day; MOE = 580) and children (exposure = 0.042 mg/kg/day, MOE = 240) (see Table 6.3.1). These exposures were higher than those calculated for the registered turf and pet uses (Memo, J. Tyler *et al.*, 6/30/09; D365445). Therefore, the short-term crack and crevice and bed-bug treatment exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of short-term aggregate risk for the U.S. population and children 1-2 years old (the child population subgroup with the highest estimated chronic dietary food exposure) (see Table 7.2). As the short-term aggregate MOEs are greater than 100, risks are not of concern.

Population Subgroups	Short-Term Scenario					
	NOAEL (mg/kg/day)	Level of Concern ¹	Max Exposure ² (mg/kg/day)	Average Dietary Exposure (mg/kg/day)	Residential Exposure ³ (mg/kg/day)	Aggregate MOE (dietary and residential) ⁴
U.S. Population	10	100	0.1	0.006091	0.017	430
Children 1-2 years old	10	100	0.1	0.018401	0.042	170

¹ The level of concern (target MOE) includes 10X for interspecies extrapolation and 10X for intraspecies variation.

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

³ Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure].

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

7.3 Intermediate-Term Aggregate Risk

The intermediate-term aggregate risk assessment estimates risks likely to result from 1 to 6 month exposures to imidacloprid residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used and average values are used for food and drinking water exposures.

Intermediate-term aggregate risk assessments are necessary for both adults and children as there is potential for both intermediate-term dermal and inhalation handler exposure, and intermediate-term post-application exposure from the residential uses of imidacloprid. For the intermediate-term aggregate risk assessment, potential residential post-application exposures were combined with food and drinking water exposures. Toddlers' residential intermediate-term aggregate exposure includes dermal and inhalation exposure from the crack and crevice uses, dermal exposure from the bed-bug uses, and incidental oral exposure from hand-to-mouth contact with treated surfaces. Adult intermediate-term aggregate exposure includes dermal and inhalation exposure from indoor crack and crevice uses, and dermal exposure from the bed-bug uses. See Table 6.3.1 for more information on combined exposures.

The combined intermediate-term exposure from residential crack and crevice and bed-bug treatment resulted in the highest exposure for adults (exposure = 0.017 mg/kg/day; MOE = 540) and children (exposure = 0.042 mg/kg/day, MOE = 260) (see Table 6.3.1). These exposures were higher than those calculated for the registered turf and pet uses (Memo, J. Tyler *et al.*, 6/30/09;

D365445). Therefore, the intermediate-term crack and crevice and bed-bug treatment exposure estimates were aggregated with the chronic dietary (food) exposures to provide a worst-case estimate of intermediate-term aggregate risk for the U.S. population and children 1-2 years old (the child population subgroup with the highest estimated chronic dietary food exposure) (see Table 7.3). As the intermediate-term aggregate MOEs are greater than 100, risks are not of concern.

Population Subgroups	Intermediate-Term Scenario					
	NOAEL (mg/kg/day)	Level of Concern ¹	Max Exposure ² (mg/kg/day)	Average Dietary Exposure (mg/kg/day)	Residential Exposure ³ (mg/kg/day)	Aggregate MOE (dietary and residential) ⁴
U.S. Population	10	100	0.1	0.006091	0.017	400
Children 1-2 years old	10	100	0.1	0.018401	0.042	150

¹ The level of concern (target MOE) includes 10X for interspecies extrapolation and 10X for intraspecies variation.

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

³ Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure].

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

7.4 Chronic Aggregate Risk

The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of imidacloprid (food and drinking water) and residential uses. However, due to the use patterns, no chronic residential exposures are expected. Therefore, the chronic aggregate risk assessment will consider exposure from food and drinking water only. The chronic dietary exposure estimates are below HED's level of concern (<100% cPAD) for the general U.S. population (11% of the cPAD) and all population subgroups (see Table 5.2). The most highly exposed population subgroup is children 1-2 years old, at 32% of the cPAD. Therefore, the chronic aggregate risk associated with the proposed use of imidacloprid does not exceed HED's level of concern for the general U.S. population or any population subgroups.

8.0 Cumulative Risk Characterization/Assessment

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to imidacloprid and any other substances and imidacloprid 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 imidacloprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

9.0 Occupational Exposure/Risk Pathway

It is anticipated that there will be occupational handler and post-application exposure from the proposed uses of imidacloprid. Occupational exposure is expected for the residential crack and crevice and bed-bug uses in addition to the proposed agricultural uses. The occupational exposure assessment for the seed treatment uses was provided in a HED memorandum by K. Lowe (Memo, 10/13/09; DP# 370461) and the occupational exposure assessment for the residential crack and crevice and bed-bug uses was provided in a HED memorandum by K. Lowe (Memo, 11/23/09; DP#367396).

Based on label information, exposure is expected to occur for short- and intermediate-term durations.

9.1 Occupational Handler Exposures and Risks

Commercial seed-treatment equipment is designed to apply accurately measured quantities of pesticides to a given weight or quantity of seed. For all crops, potential occupational exposure scenarios from use of imidacloprid as a commercial seed treatment include:

- Mixing, loading, applying wettable powder formulations;
- Bagging treated seed;
- Sewing bags;
- Multiple activities; and
- Planting treated seed.

Typically for large-scale commercial seed treatments, handlers perform only those specific individual tasks listed above; however, it is assumed that handlers also may perform multiple activities throughout the day. As a result a "multiple activities" scenario (i.e., where one handler performs all seed-treatment tasks such as loading/applying, sewing, bagging, cleaning, calibration, repair, forklift driver, etc.) is included. Planting treated seed consists of the grower purchasing bags of treated seed, placing the seed in the hopper, and applying seed to fields. This is considered a secondary handler exposure scenario.

For potato seed pieces, possible exposure from use of imidacloprid as a commercial seed treatment may occur during the following scenarios:

- Loading, and applying wettable powder formulation to the seed pieces;
- Cutting/sorting treated seed pieces;
- Loading treated seed pieces into trucks; and
- Planting treated seed pieces.

Potential occupational exposure scenarios for the on-farm seed treatment of cereal grains and potato seed pieces include:

- Mixing, loading, applying wettable-powder formulations; and
- Planting treated seed.

Potential occupational exposure scenarios for soil-directed treatment of bulb vegetables include:

- Mixing/loading liquids to support chemigation applications,
- Mixing/loading liquids to support groundboom applications,
- Applying sprays with groundboom equipment,
- Mixing/loading/applying sprays with low-pressure handwand, and
- Mixing/loading/applying sprays with handgun equipment.

Potential occupational exposure scenarios for the bed-bug and crack and crevice uses include:

- Mixing/loading/applying sprays with low-pressure handwand.

Chemical-specific data for assessing exposure from the proposed uses of imidacloprid were not submitted to the Agency in support of this Section 3 application. Unit exposure data from PHED, ORETF, and HED ExpoSAC Policy 14: SOPs for Seed Treatment were used in this assessment. Unit exposure data for mixing/loading wettable powder formulations from PHED was used as a surrogate for the loader/applicator seed-treatment scenarios, since no seed-treatment-specific unit exposure values are available for wettable powder formulations. Since the loader/applicator unit exposure value from ExpoSAC Policy 14 includes the use of chemical-resistant gloves, the PHED unit exposure value for baseline plus gloves was used instead of the baseline unit exposure value.

For purposes of performing commercial and on-farm seed-treatment assessments, HED primarily used ExpoSAC Policy 15 to estimate amount of seeds treated per day and seeds planted per day.

For potato seed-piece treatment, information from industry was used for both commercial and on-farm seed-treatment assessments. In a previous occupational risk assessment for potato seed pieces, HED contacted persons in the potato industry for input (Memo, T. Dole, 6/8/05, D291663). Based on that input, HED assumed that 500 tons (1,000,000 pounds) of seed pieces are commercially treated per day and 30 tons (60,000 pounds) of potato seed pieces are treated by on-farm seed-piece treaters. In addition, HED assumes that the amount of potato seed pieces planted per day is assumed to be 50 tons (100,000 pounds). The industry estimated that approximately 1 ton of potato seed-pieces are planted per acre and approximately 40 acres are planted each day. In another previous occupational risk assessment for potato seed pieces, HED assumed 50 A/day may be planted (Memo, M. Dow, 9/11/07, D343132). The higher number was used because planters vary in capacity and capability, and some of the larger planters are 6-row and 8-row planters.

For purposes of assessing a crack and crevice exposure scenario for commercial applicators, HED used the mixing/loading/applying wettable powders with a low-pressure handwand scenario as a surrogate to assess handler exposure. The unit exposure values provided for the wettable powder/low-pressure handwand scenario are based on actual exposures measured during crack and crevice applications; whereas, the unit exposure values for the liquid

formulation are based on applications to chicken houses and greenhouses. Therefore, although the Temprid™ SC Insecticide is formulated as a liquid, HED believes that the use of unit exposure values resulting from crack and crevice applications provides a more accurate representation of handler exposure.

The average adult weight of 70 kg was used for estimating dermal and inhalation exposure. It is anticipated that occupational imidacloprid exposures will generally occur in short- (1-30 days) and intermediate- (1-6 months) term durations. Since the short- and intermediate-term adult dermal endpoints were based on an oral study, a 7.2% dermal-absorption factor was used to estimate dermal exposure for all durations. Since no inhalation-absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure.

Daily handler exposures are estimated for each applicable handler task with the application rate, the amount of seed treated/planted in a day or the area treated in a day, and the applicable unit exposure using the following formula:

$$\text{Daily Exposure (mg ai/day)} = \text{Unit Exposure (\mu g ai/lb ai handled)} * \text{Application Rate (lbs ai)} * \text{Daily Amount Handled (lbs/day)} * \text{Conversion Factor (mg/1,000 \mu g)}$$

Where:

Daily Exposure	=	Amount (mg ai/day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption;
Unit Exposure	=	Unit exposure value ($\mu\text{g ai/day}$),
Application Rate	=	Normalized application rate based on a logical unit treatment, such as pounds seed or acres (lb ai/lb seed or lb ai/A), and
Daily Amount Handled	=	Amount seed treated/planted per day (lb seed/day) or area treated per day (A/day).

Daily dose (dermal or inhalation) was calculated by normalizing the daily dermal or inhalation exposure value by body weight and accounting for dermal and inhalation absorption.

$$\text{Average Daily Dose (mg/kg/day)} = \text{Daily Exposure (mg ai/day)} * (\text{Absorption Factor (\%/100)}) / \text{Body Weight (kg)}$$

Where:

Average Daily Dose	=	Absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day),
Daily Exposure	=	Amount (mg ai/day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption,
Absorption Factor	=	A measure of the amount of chemical that crosses a biological boundary such as the skin or lungs, and
Body Weight	=	Body weight determined to represent the population of interest in a risk assessment.

The daily dermal and inhalation doses received by occupational handlers were compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational handlers for each exposure route. All MOE values were calculated separately for dermal and inhalation exposure levels using the following formula:

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

Where:

- MOE = Margin of exposure value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless),
- ADD = Average daily dose (ADD) is absorbed dose received from exposure to pesticide, and
- NOAEL = Dose level in a toxicity study, where no observed adverse effects occurred in the study.

When the dermal and inhalation PODs are based on the same toxicological effects, the risks may be combined to determine a total risk using the following formula:

$$\text{TOTAL MOE} = \text{NOAEL (mg/kg/day)} / (\text{Dermal dose} + \text{Inhalation dose (mg/kg/day)})$$

Summaries of the short- and intermediate-term occupational handler risks for commercial seed treatment, on-farm seed treatment, planters, and soil-directed applications to bulb vegetables are listed in Attachment 4.

Commercial Seed Treatment

For all vegetable crops, all seed-treatment handler scenarios assessed resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100) with either baseline attire (i.e., single layer of clothing, no gloves, no respirator) or with additional PPE (e.g., gloves, respirator). When assessed using the HED default of 5,500 pounds of seeds treated per day, most scenarios did not have risks of concern with the label recommended PPE (i.e., single layer of clothing, gloves and a PF-5 respirator). However, for lettuce (head and leaf), cabbage, and broccoli, MOEs exceeded HED's level of concern unless engineering controls were used (i.e., water-soluble bags). When these scenarios are assessed using the proposed value of 500 pounds of seed treated per day, MOEs do not exceed HED's level of concern when chemical-resistant gloves are worn in addition to the baseline attire. **HED recommends that either water-soluble bags be required for the seed treatment product or the label includes a restriction to 500 lb seed treated/day for all vegetable crops.**

For cereal grains and potato seed pieces, all seed-treatment handler scenarios resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100) with either baseline attire (i.e., single layer of clothing, no gloves, no respirator) or with additional PPE (e.g., gloves, respirator).

On-farm Seed Treatment

For cereal grains and potato seed pieces, all on-farm seed-treatment handler scenarios resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100) with either baseline attire (i.e., single layer of clothing, no gloves, no respirator) or with additional PPE (e.g., gloves, respirator).

Seed Planting

Risks from planting treated seeds resulted in MOEs that do not exceed HED's level of concern (i.e., MOEs ≥ 100) when chemical-resistant gloves are worn in addition to the baseline attire. Dermal unit exposure data are not available at the baseline level of mitigation for this scenario. **HED recommends that RD ensure that appropriate language is placed on the product label to include the appropriate PPE for planters of treated seed.**

Soil-directed Treatment - Bulb Vegetables

The results of the occupational handler exposure and risk assessment for bulb vegetables indicate that MOEs do not exceed HED's level of concern (i.e., $MOEs \geq 100$) with either baseline attire (i.e., single layer of clothing, no respirator) or with the addition of gloves as recommended on the label.

Crack and Crevice and Bed-Bug Uses

The results of the occupational handler exposure and risk assessment indicate that MOEs do not exceed HED's level of concern (i.e., $MOEs \geq 100$) with either baseline attire (i.e., single layer of clothing, no respirator) or with the addition of gloves as recommended on the label.

9.2 Occupational Post-application Exposures and Risks

There is the possibility for agricultural workers to have post-application exposure to imidacloprid following the planting of treated seeds or soil-directed treatment of bulb vegetables. HED assumes that inhalation exposures are minimal following outdoor applications of an active ingredient with low vapor pressure. Since imidacloprid is applied only in outdoor settings and has a low vapor pressure (4×10^{-7} mPa at 20°C), post-application inhalation exposures and risks were not assessed. Currently, HED has no data to assess post-application dermal exposures to soil by occupational workers; therefore, for the proposed soil-directed uses and planting of treated seed, post-application dermal exposures and risks to occupational workers were not assessed.

For the crack and crevice and bed-bug uses, HED believes the presence of commercial handlers in treated residential areas is minimal after application. Therefore, a post-application quantitative assessment for the commercial handlers for this product was not conducted.

9.3 REI

Since no quantitative post-application assessment was completed for treated seeds or soil-directed treatment of bulb vegetables, the REI is based on the acute toxicity of imidacloprid, which is classified as Category IV for acute dermal toxicity and for skin and eye irritation potential. Imidacloprid is not a dermal sensitizer. Under the WPS for Agricultural Pesticides, the default REI is 12 hours for active ingredients classified as acute Toxicity Categories III or IV for these routes of entry. The WPS allows workers to enter treated areas without restriction if there will be no contact with anything that has been treated with the pesticide. For purposes of seed treatment (once the seeds are planted) or soil-directed treatment of bulb vegetables, workers can enter during the REI, provided they do not contact the soil/media subsurface. Certain tasks may involve contact with the soil subsurface (e.g., repair of certain irrigation equipment) and they are covered by the REI. Therefore, HED concurs with the 12-hour REI on the proposed label for seed treatment and soil-directed treatment of bulb vegetables. **HED recommends that the appropriate language is placed on the product label to include the REI following the planting of treated seed.** The labeling should state the following:

Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag.

"Treated Seed - Do Not Use for Food, Feed, or Oil Purposes."

"When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves."

"After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."

10.0 Data Needs and Label Requirements

10.1 Toxicology

- Guideline immunotoxicity study.

10.2 Residue Chemistry

PP# 8F7414

- Revised Section F to include the recommended tolerances and correct commodity definitions.

PP# 8F7415

- Revised Section F to include the correct commodity definition.

10.3 Occupational and Residential Exposure

- Reformulation of seed-treatment product into water-soluble bags or addition of a label restriction of 500 lb seed treated/day for all vegetable crops.
- Revised Section B to include the following language:

Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag.

"Treated Seed - Do Not Use for Food, Feed, or Oil Purposes."

"When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves."

"After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are

planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface.”

Attachments

Attachment 1: Toxicity Profile Tables.

Attachment 2: Structures of Imidacloprid Metabolites.

Attachment 3: IRLS Sheet.

Attachment 4: Occupational Handler Exposure and Risk Calculations Tables.

cc: G. Kramer (RAB1)

RDI: RAB1

G.F. Kramer:S10781:PY-S:(703)305-5079:7509P:RAB1

Attachment 1: Toxicity Profile Tables

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
81-1	Acute Oral	42055331	LD ₅₀ = 424 mg/kg (M) LD ₅₀ >450 mg/kg (F)	II
81-2	Acute Dermal	42055332	LD ₅₀ >5000 mg/kg	IV
81-3	Acute Inhalation	42256317	LC ₅₀ >5.33 mL	IV
81-4	Primary Eye Irritation	42055334	Not an eye irritant	IV
81-5	Primary Skin Irritation	42055335	Not a dermal irritant	IV
81-6	Dermal Sensitization	42055336	Not a dermal sensitizer	N/A

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100 90-Day oral toxicity rodents (rats)	NA	NA
870.3150 90-Day oral toxicity (nonrodents)	NA	NA
870.3200 21/28-Day dermal toxicity (rabbits)	42256329 (1990) Acceptable/guideline 0 or 1000 mg/kg/day 6 hr/day, 5 d/week	NOAEL = 1000 mg/kg/day (HDT) LOAEL = not identified
870.3250 90-Day dermal toxicity	NA	NA
870.3465 4-Week inhalation toxicity (rat)	42273001 (1989) Acceptable/guideline 0, 0.0055, 0.035, or 0.191 mg/L/day, 6 hr/day, 5 d/week for 4 weeks	NOAEL = 0.191 mg/L/day (HDT) LOAEL = not identified
870.3700a Prenatal developmental toxicity (rats)	42256338 (1992) Acceptable/guideline F: 0, 10, 30, or 100 mg/kg/day	Maternal NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on decreased body-weight gain and decreased corrected body-weight gain. Developmental NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on a slight increase in the incidence of wavy ribs.
870.3700b Prenatal developmental toxicity (rabbits)	42256339 (1992) Acceptable/guideline F: 0, 8, 24, or 72 mg/kg/day	Maternal NOAEL = 24 mg/kg/day LOAEL = 72 mg/kg/day based on maternal deaths and decreased maternal absolute body weights, body-weight gains, and food consumption. Developmental NOAEL = 24 mg/kg/day LOAEL = 72 mg/kg/day based on abortion, total litter resorptions, increased postimplantation loss due to increased late resorptions, decreased fetal weights, and very low incidences of skeletal alterations.
870.3800 Reproduction and fertility effects (rats)	42256340 (1990) Acceptable/guideline 0, 100, 250, or 700 ppm F ₀ (M/F): 0, 8.1/8.8, 20.1/22.1, or 56.7/62.8 mg/kg/day F ₁ (M/F): 0, 6.4/7.2, 16.5/18.9, or 47.3/52.3 mg/kg/day	Parental/Systemic NOAEL = 16.5 mg/kg/day LOAEL = 47.3 mg/kg/day based on decreased pre-mating weight gain by F ₀ males and females and F ₁ females and decreased gestational weight gain by F ₁ females. Reproductive NOAEL = 47.3 mg/kg/day (HDT) LOAEL = not identified Offspring NOAEL = 16.5 mg/kg/day LOAEL = 47.3 mg/kg/day based on decreased pup body weights in both litters of both generations.
870.4100a Chronic toxicity (rodents)	NA; see 870.4300	NA
870.4100b Chronic toxicity (dogs)	42273002 (1989) Acceptable/guideline 0, 200, 500, or 1250/2500 ppm M/F: 0, 6.1, 15, or 41 (first 16 wks.), then 72 mg/kg/d	NOAEL = 72 mg/kg/day (HDT) LOAEL = not identified
870.4200a	NA; see 870.4300	NA

Table A.2. Toxicity Profile of Imidacloprid Technical.

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
Carcinogenicity (rats)		
870.4200b Carcinogenicity (mice)	42256335 (1991) Acceptable/guideline with 42256336 0, 100, 330, or 1000 ppm M: 0, 20, 66, or 208 mg/kg/day F: 0, 30, 104, or 274 mg/kg/day 42256336 (1991) 0 or 2000 ppm M: 0 or 414; F: 0 or 424 mg/kg/day	NOAEL = Males: 208 mg/kg/day; Females: 274 mg/kg/day LOAEL = Males: 414 mg/kg/day; Females: 424 mg/kg/day based on decreased body weights, food consumption and water intake. No evidence of carcinogenicity.
870.4300 Combined Chronic/carcinogenicity (rats)	42256331 (1989) Acceptable/guideline with 42256332 0, 100, 300, or 900 ppm M: 0, 5.7, 16.9, or 51.3 mg/kg/day F: 0, 7.6, 24.9, or 73.0 mg/kg/day 42256332 (1991) 0 or 1800 ppm M: 0 or 102.6; F: 0 or 143.7 mg/kg/day	NOAEL = Males: 5.7 mg/kg/day; Females: 7.6 mg/kg/day LOAEL = Males: 16.9 mg/kg/day; Females: 24.9 mg/kg/day based on thyroid toxicity (increased incidence of mineralized particles in thyroid colloid) in males. No evidence of carcinogenicity.
870.5100 Bacterial reverse mutation	42256341 Acceptable/guideline	Negative for inducing reverse mutation in bacteria exposed to doses up to 5000 ug/plate.
870.5100 Bacterial reverse mutation	42256343 Acceptable/guideline	Negative up to 12,500 ug/plate.
870.5100 Bacterial reverse mutation	42256363 Acceptable/guideline	Negative up to 5500 ug/plate.
870.5300 <i>In vitro</i> mammalian cell gene mutation	42256342 Acceptable/guideline	Negative for inducing forward mutation in Chinese Hamster Ovary (CHO) (mammalian) cells treated up to 1222 ug/mL.
870.5300 <i>In vitro</i> mammalian cell gene mutation	42256364 Acceptable/guideline	Negative up to 2000 ug/mL.
870.5300 <i>In vitro</i> mammalian cell gene mutation	42256365 Acceptable/guideline	Negative up to 2000 ug/mL.
870.5375 <i>In vitro</i> mammalian chromosome abberation (HL)	42256345 Acceptable/guideline	Positive at 500 ug/mL - S9 and 1300 ug/mL +S9, both cytotoxic doses
870.5375 <i>In vitro</i> mammalian chromosome abberation (CHV79)	42256370 Acceptable/guideline	Negative up to 1000 ug/mL.
870.5375 <i>In vitro</i> mammalian chromosome abberation (CHO)	42256371 Acceptable/guideline	Negative up to 1000 ug/mL.
870.5380 Mammalian germ cell chromosome abberation (mouse)	42256348 Unacceptable/guideline	Negative, but only tested up to 80 mg/ml.
870.5385 Mammalian bone marrow chromosome abberation (chinese hamster)	42256344 Acceptable/guideline	Negative for chromosome breakage up to 2000 ug/mL.
870.5395 Mammalian micronucleus (mouse)	42256347 Unacceptable/guideline	Negative, but only tested up to 80 mg/kg.
870.5395	42256366	Negative up to 50 mg/kg IP, toxic dose.

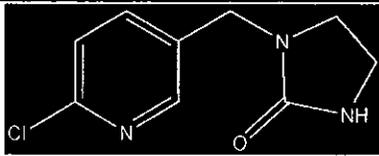
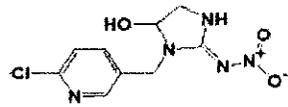
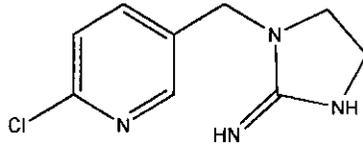
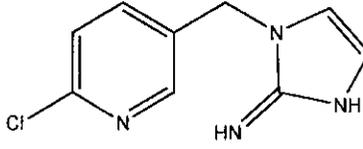
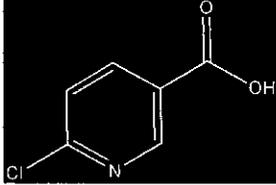
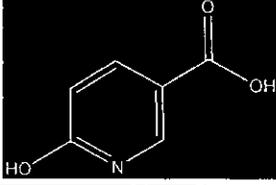
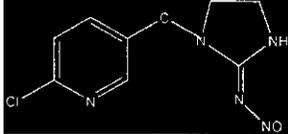
Table A.2. Toxicity Profile of Imidacloprid Technical.

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
Mammalian micronucleus (mouse)	Acceptable/guideline	
870.5395 Mammalian micronucleus (mouse)	42256367 Unacceptable/guideline	Negative up to 80 mg/kg IP, a non-toxic dose.
870.5395 Mammalian micronucleus (mouse)	42256368 Unacceptable/guideline	Negative up to 100 mg/kg PO, a non-toxic dose.
870.5395 Mammalian micronucleus (mouse)	42256369 Acceptable/guideline	Negative up to 160 mg/kg PO, toxic dose.
870.5500 DNA damage/repair <i>REC</i> assay	41156351 Acceptable/guideline	Negative up to 5000 ug/disc, the limit of solubility, with or without activation.
870.5550 Unscheduled DNA synthesis (RPH)	42256352 Acceptable/guideline	Negative up to 750 ug/mL, a cytotoxic dose.
870.5575 Mitotic gene conversion	42256353 Acceptable/guideline	Negative for crossing-over in yeast cells exposed with/without activation to precipitating levels of test article (5,000-10,000 ug/mL).
870.5550 Unscheduled DNA synthesis (RPH)	42256372 Acceptable/guideline	Negative up to cytotoxic doses (1333 ug/mL).
870.5900 <i>In vitro</i> sister chromatid exchange (CHO)	42256349 Acceptable/guideline	Positive at 500 ug/mL -S9 and 2000 ug/mL +S9, both cytotoxic doses.
870.5900 <i>In vitro</i> sister chromatid exchange (CHO)	47256350 Acceptable/guideline	Negative at cytotoxic doses of 400 ug/mL -S9 and 1250 ug/mL +S9.
870.59.15 <i>In vivo</i> sister chromatid exchange (chinese hamster bone marrow)	42256346 Acceptable/guideline	Negative up to 2000 mg/kg.
870.6200a Acute neurotoxicity screening battery rat	43170301 (1994) 43285801 (1994) Acceptable/guideline 0, 42, 151, or 307 mg/kg	NOAEL = not identified. LOAEL = 42 mg/kg based on decreased motor and locomotor activities observed in females.
870.6200b Subchronic neurotoxicity screening battery rat	43286401 (1994) Minimum 0, 150, 1000, or 3000 ppm M: 0, 9.3, 63.3, or 196 mg/kg/day F: 0, 10.5, 69.3, or 213 mg/kg/day	NOAEL = 9.3 mg/kg/day. LOAEL = 63.3 mg/kg/day based on decreased body-weight gain.
870.6300 Developmental neurotoxicity (rat)	45537501 (2001) Acceptable/non-guideline 0, 100, 250, or 750 ppm Gest.: 0, 8.0-8.3, 19.4-19.7, or 54.7-58.4 mg/kg/day Lact.: 0, 12.8-19.5, 30.0-45.4, or 80.4-155.0 mg/kg/day	Maternal NOAEL = 20 mg/kg/day. LOAEL = 55 mg/kg/day based on decreased food consumption and body-weight gain during lactation. Offspring NOAEL = 20 mg/kg/day. LOAEL = 55 mg/kg/day based on decreased body weight and body-weight gain, decreased motor activity and decreased caudate/putamen width in females.
870.7485 Metabolism and pharmacokinetics rat	42256354 (1990) 42256356 (1987) M&F: 1.0 or 20.0 mg/kg (labeled) as single oral dose or 1.0 mg/kg unlabeled orally followed by 1.0 mg/kg single oral dose (labeled) or 1.0 mg/kg (labeled) single dose IV M: 20.0 mg/kg single oral dose or 1.0 mg/kg single duodenal dose	Methylene-labeled imidacloprid was rapidly absorbed with approximately 90% of the administered dose being eliminated within 24 hours and 96% within 48 hours. There were no biologically significant differences between sexes, dose levels, or route of administration. Urinary excretion was the major route of elimination (70-80% of recovered radioactivity), with a lesser amount eliminated in feces (17-25% of recovered radioactivity). Biliary excretion was a major contributor to fecal radioactivity (36.6% vs. 4.8% of recovered radioactivity in bile-fistulated animals). Total tissue burden after 48 hours accounted for only approximately 0.5% of the recovered radioactivity, with major sites of accumulation being the liver, kidney, lung, skin, and plasma and minor sites being the brain and testes. Maximum plasma concentration occurred between 1.1 and 2.5 hours, and elimination half-lives (calculated from two exponential terms) were 3 and 26-118 hours. There were two major

Table A.2. Toxicity Profile of Imidacloprid Technical.

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
	42256357 (1991) M&F: 1.0 mg/kg single oral dose M: 1.0 or 150 mg/kg single oral dose 42256373 (1990) M: 1.0 or 150 mg/kg single oral dose or 80.0 mg/kg single oral dose after 1 year 1800 ppm 42256355 (1987) M: 1.0 mg/kg single oral or IV dose 42256358 (1990) 42256359 (1990) Acceptable/guideline	<p>evident routes of biotransformation. The first included an oxidative cleavage of the parent compound to give 6-CNA and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second included the hydroxylation of imidazolidine followed by elimination of water of the parent compound to give NTN 35884.</p> <p>In a comparison between [methylene-¹⁴C]imidacloprid and [imidazolidine-4,5-¹⁴C]imidacloprid, the rates of excretion were similar; however, the renal portion was higher with the imidazolidine-labeled test material. The imidazolidine-labeled test material also demonstrated higher accumulation in the tissues, with the major sites of accumulation being the liver, kidney, lung, and skin, and the minor sites being brain and muscle.</p> <p>In a comparison between [methylene-¹⁴C]imidacloprid and WAK 3839, there were no significant differences in the absorption, distribution, and excretion of the total radioactivity. More radioactivity was found in the tissues of the animals receiving imidacloprid at the 1.0 and 150.0 dose levels. The major sites of accumulation of WAK 3839 included lung, renal fat, liver, and kidney, with minor sites being the testis and brain. WAK 3839 was formed during pretreatment (chronic oral dosing) of imidacloprid; however, the proposed metabolic pathways of the two compounds were different.</p>
870.7600 Dermal penetration	NA	NA

Attachment 2: Structures of Imidacloprid Metabolites

Name	Structure
Imidacloprid urea 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidinone	
Imidacloprid hydroxy (WAK 4103)	
Imidacloprid guanidine (WAK 4140) 1-[(6-chloro-3-pyridinyl)methyl]-4,5-dihydro-1H-imidazol-2-amine	
Imidacloprid olefin (WAK 3745) 1-[(6-chloro-3-pyridinyl)methyl]-4,5-dihydro-1H-imidazol-2H-imidazol-2-imine	
6-CNA 6-chloronicotinic acid	
6-hydroxynicotinic acid	
WAK 3839	

Imidacloprid

Human-Health Risk Assessment

DP# 375406

Attachment 3: IRLS Sheet

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: 1-[(6-chloro-3-pyridinyl)methyl]-<i>N</i>-nitro-2-imidazolidinimine	Common Name: Imidacloprid	<input checked="" type="checkbox"/> Proposed tolerance <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	Date: 3/25/09
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
<input type="checkbox"/> No Codex proposal step 6 or above <input type="checkbox"/> No Codex proposal step 6 or above for the crops requested		Petition Number: 8F7414, 8F7415 DP#s: 357031, 357032 Other Identifier:	
Residue definition (step 8/CXL): sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid.		Reviewer/Branch: J. Tyler/RAB1 Residue definition: combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		vegetable, bulb, group 3	2.5
cereal grains	0.05	cereal, grain, group 15	0.05
leek	0.05 (*)		
onion, bulb	0.1		
Limits for Canada		Limits for Mexico	
<input type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested		<input type="checkbox"/> No Limits <input checked="" type="checkbox"/> No Limits for the crops requested (as of 2004)	
Residue definition: 1-[(6-chloro-3-pyridinyl)methyl]- <i>N</i> -nitro-1 <i>H</i> -imidazol-2-amine, including metabolites containing the 6-chloropicolyl moiety		Residue definition: imidacloprid	
Crop(s)	MRL (mg/kg) ¹	Crop(s)	MRL (mg/kg)
field corn	0.05		
sweet corn	0.05		
Notes/Special Instructions: S. Funk, 03/25/2009.			

Attachment 4: Occupational Handler Exposure and Risk Calculations Tables

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Radish, Cucumber [application rate^b = 1.3 lb ai/100 lb seed]																	
Loader/Applicator	5,500	72	NA	0.17	43	8.6	NA	0.013	0.044	0.0088	NA	800	230	1,100	NA	180	470
Sewer			0.0062	No Data	0.23	0.046	0.00046	No Data	0.00023	0.000047	22,000	No Data	43,000	210,000	14,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00067	No Data	0.00016	0.000033	15,000	No Data	61,000	310,000	12,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0031	0.0016	0.00033	No Data	3,200	6,100	31,000	No Data	2,100	2,900
Loader/Applicator	500	72	NA	0.17	43	8.6	NA	0.0011	0.004	0.0008	NA	8,800	2,500	13,000	NA	1,900	5,200
Sewer			0.0062	No Data	0.23	0.046	0.000041	No Data	0.000021	0.0000043	240,000	No Data	470,000	2,300,000	160,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000061	No Data	0.000015	0.000003	160,000	No Data	670,000	3,400,000	130,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00028	0.00015	0.00003	No Data	36,000	67,000	340,000	No Data	23,000	32,000
Carrot [application rate = 3.1 lb ai/100 lb seed]																	
Loader/Applicator	5,500	171	NA	0.17	43	8.6	NA	0.03	0.1	0.021	NA	340	95	480	NA	74	200
Sewer			0.0062	No Data	0.23	0.046	0.0011	No Data	0.00056	0.00011	9,200	No Data	18,000	89,000	6,100	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0016	No Data	0.00039	0.000078	6,300	No Data	26,000	130,000	5,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0074	0.0039	0.00078	No Data	1,400	2,600	13,000	No Data	890	1,200

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Loader/Applicator	500	171	NA	0.17	43	8.6	NA	0.0027	0.0095	0.0019	NA	3,700	1,100	5,300	NA	820	2,200
Sewer			0.0062	No Data	0.23	0.046	0.000099	No Data	0.000051	0.00001	100,000	No Data	200,000	980,000	67,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00015	No Data	0.000035	0.0000071	69,000	No Data	280,000	1,400,000	55,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00067	0.00035	0.000071	No Data	15,000	28,000	140,000	No Data	9,800	14,000
Onion (bulb), Melon [application rate = 1.5 lb ai/100 lb seed]																	
Loader/Applicator	5,500	83	NA	0.17	43	8.6	NA	0.014	0.051	0.01	NA	690	200	990	NA	150	410
Sewer			0.0062	No Data	0.23	0.046	0.00053	No Data	0.00027	0.000054	19,000	No Data	37,000	180,000	13,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00077	No Data	0.00019	0.000038	13,000	No Data	53,000	270,000	10,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0036	0.0019	0.00038	No Data	2,800	5,300	27,000	No Data	1,800	2,500
Loader/Applicator	500	83	NA	0.17	43	8.6	NA	0.0013	0.0046	0.00092	NA	7,600	2,200	11,000	NA	1,700	4,500
Sewer			0.0062	No Data	0.23	0.046	0.000048	No Data	0.000025	0.0000049	210,000	No Data	410,000	2,000,000	140,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00007	No Data	0.000017	0.0000034	140,000	No Data	580,000	2,900,000	110,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00032	0.00017	0.000034	No Data	31,000	58,000	290,000	No Data	20,000	28,000
Leek [application rate = 2.3 lb ai/100 lb seed]																	
Loader/Applicator	5,500	127	NA	0.17	43	8.6	NA	0.022	0.078	0.016	NA	450	130	640	NA	100	270

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Sewer			0.0062	No Data	0.23	0.046	0.00081	No Data	0.00042	0.000083	12,000	No Data	24,000	120,000	8,200	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0012	No Data	0.00029	0.000058	8,400	No Data	35,000	170,000	6,800	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0055	0.0029	0.00058	No Data	1,800	3,500	17,000	No Data	1,200	1,700
Loader/Applicator			NA	0.17	43	8.6	NA	0.002	0.0071	0.0014	NA	5,000	1,400	7,100	NA	1,100	2,900
Sewer	500	127	0.0062	No Data	0.23	0.046	0.000073	No Data	0.000038	0.0000076	140,000	No Data	260,000	1,300,000	90,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00011	No Data	0.000026	0.0000053	93,000	No Data	380,000	1,900,000	75,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0005	0.00026	0.000053	No Data	20,000	38,000	190,000	No Data	13,000	18,000
Loader/Applicator			NA	0.17	43	8.6	NA	0.0083	0.029	0.0058	NA	1,200	340	1,700	NA	270	710
Onion (bunching) [application rate = 0.86 lb ai/100 lb seed]																	
Sewer	5,500	47	0.0062	No Data	0.23	0.046	0.0003	No Data	0.00016	0.000031	33,000	No Data	64,000	320,000	22,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00044	No Data	0.00011	0.000022	23,000	No Data	92,000	460,000	18,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.002	0.0011	0.00022	No Data	4,900	9,200	46,000	No Data	3,200	4,400
Loader/Applicator			NA	0.17	43	8.6	NA	0.00075	0.0026	0.00053	NA	13,000	3,800	19,000	NA	2,900	7,800
Sewer	500	47	0.0062	No Data	0.23	0.046	0.000027	No Data	0.000014	0.0000028	360,000	No Data	710,000	3,500,000	240,000	No Data	No Data

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Bagger			0.0091	No Data	0.16	0.032	0.00004	No Data	0.0000098	0.000002	250,000	No Data	1,000,000	5,100,000	200,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00019	0.000098	0.00002	No Data	54,000	100,000	510,000	No Data	35,000	49,000
Lettuce (head) [application rate = 24 lb ai/100 lb seed]																	
Loader/Applicator	5,500	1320	NA	0.17 (0.13 for DL w/gloves; 0.0098 for eng cont)	43	8.6 (4.3 for PF-10 R; 0.24 for eng cont)	NA	0.23 (0.20 for DL w/gloves; 0.013 for eng cont)	0.81	0.16 (0.081 for PF-10 R; 0.0045 for eng cont)	NA	43 (57 for DL w/gloves; 750 for eng cont)	12	62 (120 for PF-10 R; 2,200 for eng cont)	NA	10	25 (39 for DL w/gloves + PF-10 R; 560 for eng cont)
Sewer			0.0062	No Data	0.23	0.046	0.0084	No Data	0.0043	0.00087	1,200	No Data	2,300	12,000	780	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.012	No Data	0.003	0.0006	810	No Data	3,300	17,000	650	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.057	0.03	0.006	No Data	180	330	1,700	No Data	110	160
Loader/Applicator	500	1320	NA	0.17	43	8.6	NA	0.021	0.074	0.015	NA	480	140	680	NA	110	280
Sewer			0.0062	No Data	0.23	0.046	0.00077	No Data	0.00039	0.000079	13,000	No Data	25,000	130,000	8,600	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0011	No Data	0.00027	0.000055	8,900	No Data	36,000	180,000	7,200	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0052	0.0027	0.00055	No Data	1,900	3,600	18,000	No Data	1,300	1,700
Lettuce (leaf) [application rate = 23 lb ai/100 lb seed]																	
Loader/Applicator	5,500	1265	NA	0.17 (0.13 for	43	8.6 (4.3 for	NA	0.22 (0.20 for	0.78	0.16 (0.078 for	NA	45 (59 for DL	13	64 (130 for	NA	10	27 (41 for DL

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
				DL w/gloves; 0.0098 for eng cont)		PF-10 R; 0.24 for eng cont)		DL w/gloves; 0.013 for eng cont)		PF-10 R; 0.0043 for eng cont)		w/gloves; 780 for eng cont)		PF-10 R; 2,300 for eng cont)			w/gloves + PF-10 R; 590 for eng cont)
Sewer			0.0062	No Data	0.23	0.046	0.0081	No Data	0.0042	0.00083	1,200	No Data	2,400	12,000	820	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.012	No Data	0.0029	0.00058	840	No Data	3,500	17,000	680	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.055	0.029	0.0058	No Data	180	350	1,700	No Data	120	170
Loader/Applicator			NA	0.17	43	8.6	NA	0.02	0.071	0.014	NA	500	140	710	NA	110	290
Sewer	500	1265	0.0062	No Data	0.23	0.046	0.00073	No Data	0.00038	0.000076	14,000	No Data	26,000	130,000	9,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0011	No Data	0.00026	0.000053	9,300	No Data	38,000	190,000	7,500	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.005	0.0026	0.00053	No Data	2,000	3,800	19,000	No Data	1,300	1,800
Spinach [application rate = 0.51 lb ai/100 lb seed]																	
Loader/Applicator			NA	0.17	43	8.6	NA	0.0049	0.017	0.0034	NA	2,000	580	2,900	NA	450	1,200
Sewer	5,500	28	0.0062	No Data	0.23	0.046	0.00018	No Data	0.000092	0.000018	56,000	No Data	110,000	540,000	37,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00026	No Data	0.000064	0.000013	38,000	No Data	160,000	780,000	31,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0012	0.00064	0.00013	No Data	8,300	16,000	78,000	No Data	5,400	7,500

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Loader/Applicator	500	28	NA	0.17	43	8.6	NA	0.00045	0.0016	0.00031	NA	22,000	6,400	32,000	NA	5,000	13,000
Sewer			0.0062	No Data	0.23	0.046	0.000016	No Data	0.0000084	0.0000017	610,000	No Data	1,200,000	6,000,000	410,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000024	No Data	0.0000058	0.0000012	420,000	No Data	1,700,000	8,600,000	340,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00011	0.000058	0.000012	No Data	91,000	170,000	860,000	No Data	59,000	82,000
Squash (winter), Squash (summer) [application rate = 0.23 lb ai/100 lb seed]																	
Loader/Applicator	5,500	13	NA	0.17	43	8.6	NA	0.0022	0.0078	0.0016	NA	4,500	1,300	6,400	NA	1,000	2,700
Sewer			0.0062	No Data	0.23	0.046	0.000081	No Data	0.000042	0.0000083	120,000	No Data	240,000	1,200,000	82,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00012	No Data	0.000029	0.0000058	84,000	No Data	350,000	1,700,000	68,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00055	0.00029	0.000058	No Data	18,000	35,000	170,000	No Data	12,000	17,000
Loader/Applicator	500	13	NA	0.17	43	8.6	NA	0.0002	0.00071	0.00014	NA	50,000	14,000	71,000	NA	11,000	29,000
Sewer			0.0062	No Data	0.23	0.046	0.0000073	No Data	0.0000038	0.00000076	1,400,000	No Data	2,600,000	13,000,000	900,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000011	No Data	0.0000026	0.00000053	930,000	No Data	3,800,000	19,000,000	750,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00005	0.000026	0.0000053	No Data	200,000	380,000	1,900,000	No Data	130,000	180,000
Tomato [application rate = 1.1 lb ai/100 lb seed]																	
Loader/Applicator	5,500	61	NA	0.17	43	8.6	NA	0.011	0.037	0.0074	NA	950	270	1,300	NA	210	560

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Sewer	500	61	0.0062	No Data	0.23	0.046	0.00039	No Data	0.0002	0.00004	26,000	No Data	50,000	250,000	17,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00057	No Data	0.00014	0.000028	18,000	No Data	72,000	360,000	14,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0026	0.0014	0.00028	No Data	3,800	7,200	36,000	No Data	2,500	3,500
Loader/Applicator			NA	0.17	43	8.6	NA	0.00096	0.0034	0.00068	NA	10,000	3,000	15,000	NA	2,300	6,100
Sewer	500	61	0.0062	No Data	0.23	0.046	0.000035	No Data	0.000018	0.0000036	290,000	No Data	550,000	2,800,000	190,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000051	No Data	0.000013	0.0000025	190,000	No Data	800,000	4,000,000	160,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00024	0.00013	0.000025	No Data	42,000	80,000	400,000	No Data	28,000	38,000
Loader/Applicator			NA	0.17	43	8.6	NA	0.00096	0.0034	0.00068	NA	10,000	3,000	15,000	NA	2,300	6,100
Pepper (bell, non-bell) [application rate = 2.5 lb ai/100 lb seed]																	
Loader/Applicator	5,500	138	NA	0.17	43	8.6	NA	0.024	0.084	0.017	NA	420	120	590	NA	92	240
Sewer			0.0062	No Data	0.23	0.046	0.00088	No Data	0.00045	0.00009	11,000	No Data	22,000	110,000	7,500	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0013	No Data	0.00031	0.000063	7,800	No Data	32,000	160,000	6,200	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0059	0.0031	0.00063	No Data	1,700	3,200	16,000	No Data	1,100	1,500
Loader/Applicator	500	138	NA	0.17	43	8.6	NA	0.0022	0.0077	0.0015	NA	4,600	1,300	6,500	NA	1,000	2,700
Sewer			0.0062	No Data	0.23	0.046	0.00008	No Data	0.000041	0.0000082	130,000	No Data	240,000	1,200,000	83,000	No Data	No Data

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Bagger			0.0091	No Data	0.16	0.032	0.00012	No Data	0.000029	0.0000057	85,000	No Data	350,000	1,800,000	69,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00054	0.00029	0.000057	No Data	19,000	35,000	180,000	No Data	12,000	17,000
Cabbage, Broccoli [application rate = 12 lb ai/100 lb seed]																	
Loader/Applicator	5,500	660	NA	0.17 (0.13 for DL w/gloves; 0.0098 for eng cont)	43	8.6 (4.3 for PF-10 R; 0.24 for eng cont)	NA	0.12 (0.10 for DL w/gloves; 0.0067 for eng cont)	0.41	0.081 (0.041 for PF-10 R; 0.0023 for eng cont)	NA	87 (110 for DL w/gloves; 1,500 for eng cont)	25	120 (250 for PF-10 R; 4,400 for eng cont)	NA	19	51 (78 for DL w/gloves + PF-10 R; 1,100 for eng cont)
Sewer			0.0062	No Data	0.23	0.046	0.0042	No Data	0.0022	0.00043	2,400	No Data	4,600	23,000	1,600	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0062	No Data	0.0015	0.0003	1,600	No Data	6,600	33,000	1,300	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.029	0.015	0.003	No Data	350	660	3,300	No Data	230	320
Loader/Applicator	500	660	NA	0.17	43	8.6	NA	0.01	0.037	0.0074	NA	950	270	1,400	NA	210	560
Sewer			0.0062	No Data	0.23	0.046	0.00038	No Data	0.0002	0.000039	26,000	No Data	51,000	250,000	17,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00056	No Data	0.00014	0.000027	18,000	No Data	73,000	360,000	14,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0026	0.0014	0.00027	No Data	3,900	7,300	36,000	No Data	2,500	3,500
Mustard green [application rate = 1.7 lb ai/100 lb seed]																	
Loader/Applicator	5,500	94	NA	0.17	43	8.6	NA	0.016	0.057	0.011	NA	610	170	870	NA	140	360

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Sewer	500	94	0.0062	No Data	0.23	0.046	0.0006	No Data	0.00031	0.000061	17,000	No Data	33,000	160,000	11,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00088	No Data	0.00021	0.000043	11,000	No Data	47,000	230,000	9,200	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.004	0.0021	0.00043	No Data	2,500	4,700	23,000	No Data	1,600	2,200
Loader/Applicator			NA	0.17	43	8.6	NA	0.0015	0.0052	0.001	NA	6,700	1,900	9,600	NA	1,500	4,000
Sewer	500	94	0.0062	No Data	0.23	0.046	0.000054	No Data	0.000028	0.0000056	180,000	No Data	360,000	1,800,000	120,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00008	No Data	0.000019	0.0000039	130,000	No Data	510,000	2,600,000	100,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00037	0.00019	0.000039	No Data	27,000	51,000	260,000	No Data	18,000	25,000
Loader/Applicator			NA	0.17	43	8.6	NA	0.029	0.1	0.02	NA	350	99	490	NA	77	200
Barley, Buckwheat, Rye, Sorghum, Triticale, Wheat [application rate = 0.023 lb ai/100 lb seed]																	
Sewer	718,000	165	0.0062	No Data	0.23	0.046	0.0011	No Data	0.00054	0.00011	9,500	No Data	18,000	92,000	6,300	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0015	No Data	0.00038	0.000075	6,500	No Data	26,000	130,000	5,200	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0071	0.0038	0.00075	No Data	1,400	2,600	13,000	No Data	920	1,300
Loader/Applicator			NA	0.17	43	8.6	NA	0.022	0.078	0.016	NA	450	130	640	NA	100	270
Corn (field and popcorn), Teosinte [application rate = 0.023 lb ai/100 lb seed]																	
Sewer	550,000	127	0.0062	No Data	0.23	0.046	0.00081	No Data	0.00042	0.000083	12,000	No Data	24,000	120,000	8,200	No Data	No Data
Loader/Applicator			NA	0.17	43	8.6	NA	0.022	0.078	0.016	NA	450	130	640	NA	100	270

Table A.4.1. Short-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Bagger			0.0091	No Data	0.16	0.032	0.0012	No Data	0.00029	0.000058	8,400	No Data	35,000	170,000	6,800	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0055	0.0029	0.00058	No Data	1,800	3,500	17,000	No Data	1,200	1,700
Potato Seed Pieces [application rate = 0.0041 lb ai/100 lb seed]																	
Loader/Applicator	1,000,000	41	NA	0.17	43	8.6	NA	0.0072	0.025	0.005	NA	1,400	400	2,000	NA	310	820

- a. HED default for lb seed treated per day from HED ExpoSAC Policy # 15 and information obtained from industry.
- b. Application Rates based on proposed uses on label for imidacloprid product Sepresto 75 WS (Reg. No. 264-xxx). Application rates in oz product/1,000 seed provided on the label were converted to lb ai/100 lb seed using information on number of seeds/lb provided by the Registrant and the % active ingredient in the product.
- c. Unit Exposures for loader/applicator from the PHED Version 1.1. Unit exposures for all other seed treatment activities from HED ExpoSAC Policy 14: SOPs for Seed Treatment.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.
- e. SL w/gloves: Baseline plus chemical-resistant gloves; DL w/gloves: Baseline plus coveralls and chemical-resistant gloves.
- f. Baseline Inhalation: No respirator; PF-5 R = A quarter-face dust/mist respirator (that provides an 80% protection factor); PF-10 R = A half- or full-face respirator with a dust/mist cartridge or canister (that provides a 90% protection factor).
- g. Eng cont: Engineering controls such as water soluble bags.
- h. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x dermal absorption factor (7.2%) / body weight (70 kg).
- i. Inhalation Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x conversion factor (1 mg/1,000 µg) / body weight (70 kg).
- j. Dermal MOE = NOAEL (10 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.
- k. Inhalation MOE = NOAEL (10 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.
- l. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).
- m. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).
- n. Combined SL w/gloves Dermal + PF-5 R Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + PF-5 R Inhalation dose).
- o. Combined DL w/gloves Dermal + PF-10 R Inhalation MOE = NOAEL (mg/kg/day) / (DL w/gloves Dermal dose + PF-10 R Inhalation dose).
- p. Combined eng cont MOE = NOAEL (mg/kg/day) / (Eng cont Dermal dose + Eng cont Inhalation dose).

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Radish, Cucumber [application rate^b = 1.3 lb ai/100 lb seed]																	
Loader/Applicator	5,500	72	NA	0.17	43	8.6	NA	0.013	0.044	0.0088	NA	740	210	1,100	NA	160	440
Sewer			0.0062	No Data	0.23	0.046	0.00046	No Data	0.00023	0.000047	20,000	No Data	40,000	200,000	13,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00067	No Data	0.00016	0.000033	14,000	No Data	57,000	280,000	11,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0031	0.0016	0.00033	No Data	3,000	5,700	28,000	No Data	2,000	2,700
Loader/Applicator	500	72	NA	0.17	43	8.6	NA	0.0011	0.004	0.0008	NA	8,200	2,300	12,000	NA	1,800	4,800
Sewer			0.0062	No Data	0.23	0.046	0.000041	No Data	0.000021	0.0000043	220,000	No Data	440,000	2,200,000	150,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000061	No Data	0.000015	0.000003	150,000	No Data	630,000	3,100,000	120,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00028	0.00015	0.00003	No Data	33,000	63,000	310,000	No Data	22,000	30,000
Carrot [application rate = 3.1 lb ai/100 lb seed]																	
Loader/Applicator	5,500	171	NA	0.17	43	8.6	NA	0.03	0.1	0.021	NA	310	89	440	NA	69	180
Sewer			0.0062	No Data	0.23	0.046	0.0011	No Data	0.00056	0.00011	8,600	No Data	17,000	83,000	5,600	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0016	No Data	0.00039	0.000078	5,800	No Data	24,000	120,000	4,700	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0074	0.0039	0.00078	No Data	1,300	2,400	12,000	No Data	830	1,100

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Loader/Applicator	500	171	NA	0.17	43	8.6	NA	0.0027	0.0095	0.0019	NA	3,400	980	4,900	NA	760	2,000
Sewer			0.0062	No Data	0.23	0.046	0.000099	No Data	0.000051	0.00001	94,000	No Data	180,000	910,000	62,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00015	No Data	0.000035	0.0000071	64,000	No Data	260,000	1,300,000	52,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00067	0.00035	0.000071	No Data	14,000	26,000	130,000	No Data	9,100	13,000
Onion (bulb), Melon [application rate = 1.5 lb ai/100 lb seed]																	
Loader/Applicator	5,500	83	NA	0.17	43	8.6	NA	0.014	0.051	0.01	NA	640	180	920	NA	140	380
Sewer			0.0062	No Data	0.23	0.046	0.00053	No Data	0.00027	0.000054	18,000	No Data	34,000	170,000	12,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00077	No Data	0.00019	0.000038	12,000	No Data	49,000	250,000	9,700	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0036	0.0019	0.00038	No Data	2,600	4,900	25,000	No Data	1,700	2,400
Loader/Applicator	500	83	NA	0.17	43	8.6	NA	0.0013	0.0046	0.00092	NA	7,100	2,000	10,000	NA	1,600	4,200
Sewer			0.0062	No Data	0.23	0.046	0.000048	No Data	0.000025	0.0000049	190,000	No Data	380,000	1,900,000	130,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00007	No Data	0.000017	0.0000034	130,000	No Data	540,000	2,700,000	110,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00032	0.00017	0.000034	No Data	29,000	54,000	270,000	No Data	19,000	26,000

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Leek [application rate = 2.3 lb ai/100 lb seed]																	
Loader/ Applicator	5,500	127	NA	0.17	43	8.6	NA	0.022	0.078	0.016	NA	420	120	600	NA	93	250
Sewer			0.0062	No Data	0.23	0.046	0.00081	No Data	0.00042	0.000083	12,000	No Data	22,000	110,000	7,600	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0012	No Data	0.00029	0.000058	7,900	No Data	32,000	160,000	6,300	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0055	0.0029	0.00058	No Data	1,700	3,200	16,000	No Data	1,100	1,500
Loader/ Applicator	500	127	NA	0.17	43	8.6	NA	0.002	0.0071	0.0014	NA	4,600	1,300	6,600	NA	1,000	2,700
Sewer			0.0062	No Data	0.23	0.046	0.000073	No Data	0.000038	0.0000076	130,000	No Data	250,000	1,200,000	84,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00011	No Data	0.000026	0.0000053	86,000	No Data	350,000	1,800,000	69,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0005	0.00026	0.000053	No Data	19,000	35,000	180,000	No Data	12,000	17,000
Onion (bunching) [application rate = 0.86 lb ai/100 lb seed]																	
Loader/ Applicator	5,500	47	NA	0.17	43	8.6	NA	0.0083	0.029	0.0058	NA	1,100	320	1,600	NA	250	660
Sewer			0.0062	No Data	0.23	0.046	0.0003	No Data	0.00016	0.000031	31,000	No Data	60,000	300,000	20,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00044	No Data	0.00011	0.000022	21,000	No Data	86,000	430,000	17,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.002	0.0011	0.00022	No Data	4,600	8,600	43,000	No Data	3,000	4,100

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Loader/ Applicator	500	47	NA	0.17	43	8.6	NA	0.00075	0.0026	0.00053	NA	12,000	3,500	18,000	NA	2,700	7,300
Sewer			0.0062	No Data	0.23	0.046	0.000027	No Data	0.000014	0.0000028	340,000	No Data	660,000	3,300,000	220,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00004	No Data	0.0000098	0.000002	230,000	No Data	950,000	4,700,000	190,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00019	0.000098	0.00002	No Data	50,000	95,000	470,000	No Data	33,000	45,000
Lettuce (head) [application rate = 24 lb ai/100 lb seed]																	
Loader/ Applicator	5,500	1320	NA	0.17 (0.13 for DL w/gloves ; 0.0098 for eng cont)	43	8.6 (4.3 for PF-10 R; 0.24 for eng cont)	NA	0.23 (0.20 for DL w/gloves ; 0.013 for eng cont)	0.81	0.16 (0.081 for PF-10 R; 0.0045 for eng cont)	NA	40 (53 for DL w/gloves ; 700 for eng cont)	11	57 (110 for PF-10 R; 2,100 for eng cont)	NA	9	24 (36 for DL w/gloves + PF-10 R; 520 for eng cont)
Sewer			0.0062	No Data	0.23	0.046	0.0084	No Data	0.0043	0.00087	1,100	No Data	2,100	11,000	730	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.012	No Data	0.003	0.0006	750	No Data	3,100	15,000	600	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.057	0.03	0.006	No Data	160	310	1,500	No Data	110	150
Loader/ Applicator	500	1320	NA	0.17	43	8.6	NA	0.021	0.074	0.015	NA	440	130	630	NA	98	260
Sewer			0.0062	No Data	0.23	0.046	0.00077	No Data	0.00039	0.000079	12,000	No Data	24,000	120,000	8,000	No Data	No Data

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Bagger			0.0091	No Data	0.16	0.032	0.0011	No Data	0.00027	0.000055	8,300	No Data	34,000	170,000	6,700	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0052	0.0027	0.00055	No Data	1,800	3,400	17,000	No Data	1,200	1,600
Lettuce (leaf) [application rate = 23 lb ai/100 lb seed]																	
Loader/ Applicator	5,500	1265	NA	0.17 (0.13 for DL w/gloves ; 0.0098 for eng cont)	43	8.6 (4.3 for PF-10 R; 0.24 for eng cont)	NA	0.22 (0.20 for DL w/gloves ; 0.013 for eng cont)	0.78	0.16 (0.078 for PF-10 R; 0.0043 for eng cont)	NA	42 (55 for DL w/gloves ; 730 for eng cont)	12	60 (120 for PF-10 R; 2,100 for eng cont)	NA	9	25 (38 for DL w/gloves + PF-10 R; 540 for eng cont)
Sewer			0.0062	No Data	0.23	0.046	0.0081	No Data	0.0042	0.00083	1,200	No Data	2,200	11,000	760	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.012	No Data	0.0029	0.00058	790	No Data	3,200	16,000	630	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.055	0.029	0.0058	No Data	170	320	1,600	No Data	110	150
Loader/ Applicator	500	1265	NA	0.17	43	8.6	NA	0.02	0.071	0.014	NA	460	130	660	NA	100	270
Sewer			0.0062	No Data	0.23	0.046	0.00073	No Data	0.00038	0.000076	13,000	No Data	25,000	120,000	8,400	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0011	No Data	0.00026	0.000053	8,600	No Data	35,000	180,000	6,900	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.005	0.0026	0.00053	No Data	1,900	3,500	18,000	No Data	1,200	1,700
Spinach [application rate = 0.51 lb ai/100 lb seed]																	

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Loader/ Applicator	5,500	28	NA	0.17	43	8.6	NA	0.0049	0.017	0.0034	NA	1,900	540	2,700	NA	420	1,100
Sewer			0.0062	No Data	0.23	0.046	0.00018	No Data	0.000092	0.000018	52,000	No Data	100,000	500,000	34,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00026	No Data	0.000064	0.000013	35,000	No Data	150,000	730,000	28,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0012	0.00064	0.00013	No Data	7,700	15,000	73,000	No Data	5,000	6,900
Loader/ Applicator	500	28	NA	0.17	43	8.6	NA	0.00045	0.0016	0.00031	NA	21,000	5,900	30,000	NA	4,600	12,000
Sewer			0.0062	No Data	0.23	0.046	0.000016	No Data	0.0000084	0.0000017	570,000	No Data	1,100,000	5,500,000	380,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000024	No Data	0.0000058	0.0000012	390,000	No Data	1,600,000	8,000,000	310,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00011	0.000058	0.000012	No Data	84,000	160,000	800,000	No Data	55,000	76,000
Squash (winter), Squash (summer) [application rate = 0.23 lb ai/100 lb seed]																	
Loader/ Applicator	5,500	13	NA	0.17	43	8.6	NA	0.0022	0.0078	0.0016	NA	4,200	1,200	6,000	NA	930	2,500
Sewer			0.0062	No Data	0.23	0.046	0.000081	No Data	0.000042	0.0000083	120,000	No Data	220,000	1,100,000	76,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00012	No Data	0.000029	0.0000058	79,000	No Data	320,000	1,600,000	63,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00055	0.00029	0.000058	No Data	17,000	32,000	160,000	No Data	11,000	15,000
Loader/ Applicator	500	13	NA	0.17	43	8.6	NA	0.0002	0.00071	0.00014	NA	46,000	13,000	66,000	NA	10,000	27,000

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.																	
Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Sewer			0.0062	No Data	0.23	0.046	0.0000073	No Data	0.0000038	0.00000076	1,300,000	No Data	2,500,000	12,000,000	840,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000011	No Data	0.0000026	0.00000053	860,000	No Data	3,500,000	18,000,000	690,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.000005	0.000026	0.0000053	No Data	190,000	350,000	1,800,000	No Data	120,000	170,000
Tomato [application rate = 1.1 lb ai/100 lb seed]																	
Loader/Applicator			NA	0.17	43	8.6	NA	0.011	0.037	0.0074	NA	880	250	1,300	NA	190	520
Sewer	5,500	61	0.0062	No Data	0.23	0.046	0.00039	No Data	0.0002	0.00004	24,000	No Data	47,000	230,000	16,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00057	No Data	0.00014	0.000028	16,000	No Data	67,000	340,000	13,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0026	0.0014	0.00028	No Data	3,600	6,700	34,000	No Data	2,300	3,200
Loader/Applicator			NA	0.17	43	8.6	NA	0.00096	0.0034	0.00068	NA	9,700	2,800	14,000	NA	2,100	5,700
Sewer	500	61	0.0062	No Data	0.23	0.046	0.000035	No Data	0.000018	0.0000036	270,000	No Data	510,000	2,600,000	170,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.000051	No Data	0.000013	0.0000025	180,000	No Data	740,000	3,700,000	150,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00024	0.00013	0.000025	No Data	39,000	74,000	370,000	No Data	26,000	35,000
Pepper (bell, non-bell) [application rate = 2.5 lb ai/100 lb seed]																	
Loader/Applicator	5,500	138	NA	0.17	43	8.6	NA	0.024	0.084	0.017	NA	390	110	550	NA	86	230

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Sewer			0.0062	No Data	0.23	0.046	0.00088	No Data	0.00045	0.00009	11,000	No Data	21,000	100,000	7,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0013	No Data	0.00031	0.000063	7,200	No Data	30,000	150,000	5,800	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0059	0.0031	0.00063	No Data	1,600	3,000	15,000	No Data	1,000	1,400
Loader/Applicator	500	138	NA	0.17	43	8.6	NA	0.0022	0.0077	0.0015	NA	4,300	1,200	6,100	NA	940	2,500
Sewer			0.0062	No Data	0.23	0.046	0.00008	No Data	0.000041	0.0000082	120,000	No Data	230,000	1,100,000	77,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00012	No Data	0.000029	0.0000057	79,000	No Data	330,000	1,600,000	64,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00054	0.00029	0.000057	No Data	17,000	33,000	160,000	No Data	11,000	16,000
Cabbage, Broccoli [application rate = 12 lb ai/100 lb seed]																	
Loader/Applicator	5,500	660	NA	0.17 (0.13 for DL w/gloves ; 0.0098 for eng cont)	43	8.6 (4.3 for PF-10 R ; 0.24 for eng cont)	NA	0.12 (0.10 for DL w/gloves ; 0.0067 for eng cont)	0.41	0.081 (0.041 for PF-10 R ; 0.0023 for eng cont)	NA	81 (110 for DL w/gloves ; 1,400 for eng cont)	23	110 (230 for PF-10 R ; 4,100 for eng cont)	NA	18	47 (72 for DL w/gloves + PF-10 R ; 1,000 for eng cont)
Sewer			0.0062	No Data	0.23	0.046	0.0042	No Data	0.0022	0.00043	2,200	No Data	4,300	21,000	1,500	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0062	No Data	0.0015	0.0003	1,500	No Data	6,200	31,000	1,200	No Data	No Data

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.029	0.015	0.003	No Data	330	620	3,100	No Data	210	290
Loader/Applicator	500	660	NA	0.17	43	8.6	NA	0.01	0.037	0.0074	NA	890	250	1,300	NA	200	520
Sewer			0.0062	No Data	0.23	0.046	0.00038	No Data	0.0002	0.000039	24,000	No Data	47,000	240,000	16,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00056	No Data	0.00014	0.000027	17,000	No Data	68,000	340,000	13,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0026	0.0014	0.00027	No Data	3,600	6,800	34,000	No Data	2,300	3,200
Mustard green [application rate = 1.7 lb ai/100 lb seed]																	
Loader/Applicator	5,500	94	NA	0.17	43	8.6	NA	0.016	0.057	0.011	NA	570	160	810	NA	130	330
Sewer			0.0062	No Data	0.23	0.046	0.0006	No Data	0.00031	0.000061	16,000	No Data	30,000	150,000	10,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00088	No Data	0.00021	0.000043	11,000	No Data	44,000	220,000	8,500	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.004	0.0021	0.00043	No Data	2,300	4,400	22,000	No Data	1,500	2,100
Loader/Applicator	500	94	NA	0.17	43	8.6	NA	0.0015	0.0052	0.001	NA	6,300	1,800	8,900	NA	1,400	3,700
Sewer			0.0062	No Data	0.23	0.046	0.000054	No Data	0.000028	0.0000056	170,000	No Data	330,000	1,700,000	110,000	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.00008	No Data	0.000019	0.0000039	120,000	No Data	480,000	2,400,000	94,000	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.00037	0.00019	0.000039	No Data	25,000	48,000	240,000	No Data	17,000	23,000

Table A.4.2. Intermediate-Term Commercial Seed Treatment Exposure and Risks.

Exposure Scenario	lbs seed treated or planted/day ^a	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f,g}				Dose ^{h,i} (mg/kg/day)				MOE ^{j,k,l,m,n,o,p} (Target = 100)						
			Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	PF-5 R Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	PF-5 R Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + PF-5 R Inhalation
Barley, Buckwheat, Rye, Sorghum, Triticale, Wheat [application rate = 0.023 lb ai/100 lb seed]																	
Loader/Applicator	718,000	165	NA	0.17	43	8.6	NA	0.029	0.1	0.02	NA	320	92	460	NA	71	190
Sewer			0.0062	No Data	0.23	0.046	0.0011	No Data	0.00054	0.00011	8,800	No Data	17,000	86,000	5,800	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0015	No Data	0.00038	0.000075	6,000	No Data	25,000	120,000	4,800	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0071	0.0038	0.00075	No Data	1,300	2,500	12,000	No Data	850	1,200
Corn (field and popcorn), Teosinte [application rate = 0.023 lb ai/100 lb seed]																	
Loader/Applicator	550,000	127	NA	0.17	43	8.6	NA	0.022	0.078	0.016	NA	420	120	600	NA	93	250
Sewer			0.0062	No Data	0.23	0.046	0.00081	No Data	0.00042	0.000083	12,000	No Data	22,000	110,000	7,600	No Data	No Data
Bagger			0.0091	No Data	0.16	0.032	0.0012	No Data	0.00029	0.000058	7,900	No Data	32,000	160,000	6,300	No Data	No Data
Multiple Activities			No Data	0.042	1.6	0.32	No Data	0.0055	0.0029	0.00058	No Data	1,700	3,200	16,000	No Data	1,100	1,500
Potato Seed Pieces [application rate = 0.0041 lb ai/100 lb seed]																	
Loader/Applicator	1,000,000	41	NA	0.17	43	8.6	NA	0.0072	0.025	0.005	NA	1,300	370	1,800	NA	290	760

- a. HED default for lb seed treated per day from HED ExpoSAC Policy # 15 and information obtained from industry.
- b. Application Rates based on proposed uses on label for imidacloprid product Sepresto 75 WS (Reg. No. 264-xxx). Application rates in oz product/1,000 seed provided on the label were converted to lb ai/100 lb seed using information on number of seeds/lb provided by the Registrant and the % active ingredient in the product.
- c. Unit Exposures for loader/applicator from the PHED Version 1.1. Unit exposures for all other seed treatment activities from HED ExpoSAC Policy 14: SOPs for Seed Treatment.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.
- e. SL w/gloves: Baseline plus chemical-resistant gloves; DL w/gloves: Baseline plus coveralls and chemical-resistant gloves.
- f. Baseline Inhalation: No respirator; PF-5 R = A quarter-face dust/mist respirator (that provides an 80% protection factor); PF-10 R = A half- or full-face respirator with a dust/mist cartridge or canister (that provides an 90% protection factor).
- g. Eng cont: Engineering controls such as water soluble bags.

- h. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x dermal absorption factor (7.2%) / body weight (70 kg).
- i. Inhalation Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x conversion factor (1 mg/1,000 µg) / body weight (70 kg).
- j. Dermal MOE = NOAEL (9.3 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.
- k. Inhalation MOE = NOAEL (9.3 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.
- l. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).
- m. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).
- n. Combined SL w/gloves Dermal + PF-5 R Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + PF-5 R Inhalation dose).
- o. Combined DL w/gloves Dermal + PF-10 R Inhalation MOE = NOAEL (mg/kg/day) / (DL w/gloves Dermal dose + PF-10 R Inhalation dose).
- p. Combined eng cont MOE = NOAEL (mg/kg/day) / (Eng cont Dermal dose + Eng cont Inhalation dose).

Table A.4.3. Short-Term On-Farm Loader/Applicator Seed Treatment Exposure and Risks.

Crop	Lb Seed treated per day ^a	App. Rate ^b (lb ai/100 lb)	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f}			Dose ^{g,h} (mg/kg/day)			MOE ^{i,j,k,l} (Target = 100)				
				Baseline Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Barley	19,000	0.023	4.37	NA	1.2	12.6	NA	0.057	0.000075	NA	180	130,000	NA	180
Buckwheat	4,000 (Registrant proposed value)		0.92	NA	1.2	12.6	NA	0.012	0.000016	NA	840	630,000	NA	840
Corn (field and popcorn), Teosinte	3,000		0.69	NA	1.2	12.6	NA	0.0089	0.000012	NA	1,100	850,000	NA	1,100
Rye	22,000		5.06	NA	1.2	12.6	NA	0.066	0.000087	NA	150	120,000	NA	150
Sorghum	800		0.18	NA	1.2	12.6	NA	0.0024	0.0000032	NA	4,200	3,200,000	NA	4,200
Triticale	20,000		4.60	NA	1.2	12.6	NA	0.06	0.000079	NA	170	130,000	NA	170
Wheat	30,000		6.90	NA	1.2	12.6	NA	0.089	0.00012	NA	110	85,000	NA	110
Potato Seed Pieces	60,000	0.0041	2.46	NA	1.2	12.6	NA	0.032	0.000042	NA	310	240,000	NA	310

- a. HED default for lb seed treated per day from HED ExpoSAC Policy # 15 and information obtained from industry.
- b. Application Rates based on proposed uses on label for imidacloprid product Sepresto 75 WS (Reg. No. 264-xxx). Application rates in oz product/1,000 seed provided on the label were converted to lb ai/100 lb seed using information on number of seeds/lb provided by the Registrant and the % active ingredient in the product.
- c. Unit Exposures from Unit Exposures for loader/applicator from PHED Version 1.1.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.
- e. SL w/gloves: Baseline plus chemical-resistant gloves.
- f. Baseline Inhalation: No respirator.
- g. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x dermal-absorption factor (7.2%) / body weight (70 kg).
- h. Inhalation Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x conversion factor (1 mg/1,000 µg) / body weight (70 kg).
- i. Dermal MOE = NOAEL (10 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.

-
- j. Inhalation MOE = NOAEL (10 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.
 - k. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).
 - l. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).

Table A.4.4. Intermediate-Term On-Farm Loader/Applicator Seed Treatment Exposure and Risks.

Crop	Lb Seed treated per day ^a	App. Rate ^b (lb ai/100 lb)	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f}			Dose ^{g,h} (mg/kg/day)			MOE ^{i,j,k,l} (Target = 100)				
				Baseline Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Barley	19,000	0.023	4.37	NA	1.2	12.6	NA	0.057	0.000075	NA	160	120,000	NA	160
Buckwheat	4,000 (Registrant proposed value)	0.023	0.92	NA	1.2	12.6	NA	0.012	0.000016	NA	780	590,000	NA	780
Corn (field and popcorn), Teosinte	3,000	0.023	0.69	NA	1.2	12.6	NA	0.0089	0.000012	NA	1,000	790,000	NA	1,000
Rye	22,000	0.023	5.06	NA	1.2	12.6	NA	0.066	0.000087	NA	140	110,000	NA	140
Sorghum	800	0.023	0.18	NA	1.2	12.6	NA	0.0024	0.0000032	NA	3,900	2,900,000	NA	3,900
Triticale	20,000	0.023	4.60	NA	1.2	12.6	NA	0.06	0.000079	NA	160	120,000	NA	160
Wheat	30,000	0.023	6.90	NA	1.2	12.6	NA	0.089	0.00012	NA	100	79,000	NA	100
Potato Seed Pieces	60,000	0.0041	2.46	NA	1.2	12.6	NA	0.032	0.000042	NA	290	220,000	NA	290

- a. HED default for lb seed treated per day from HED ExpoSAC Policy # 15 and information obtained from industry.
- b. Application Rates based on proposed uses on label for imidacloprid product Sepresto 75 WS (Reg. No. 264-xxx). Application rates in oz product/1,000 seed provided on the label were converted to lb ai/100 lb seed using information on number of seeds/lb provided by the Registrant and the % active ingredient in the product.
- c. Unit Exposures from Unit Exposures for loader/applicator from PHED Version 1.1.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.
- e. SL w/gloves: Baseline plus chemical-resistant gloves.
- f. Baseline Inhalation: No respirator.
- g. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x dermal-absorption factor (7.2%) / body weight (70 kg).
- h. Inhalation Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x conversion factor (1 mg/1,000 µg) / body weight (70 kg).
- i. Dermal MOE = NOAEL (9.3 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.
- j. Inhalation MOE = NOAEL (9.3 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.
- k. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).
- l. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).

Table A.4.5. Short-Term Secondary Handler (Planter) Seed Treatment Exposure and Risks.

Crop	Lbs seed treated or planted/day ^a	App. Rate ^b (lb ai/100 lb)	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f}			Dose ^{g,h} (mg/kg/day)			MOE ^{i,j,k,l} (Target = 100)				
				Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Radish	1,600	1.3	21	No Data	0.25	3.4	No Data	0.0053	0.001	No Data	1,900	9,900	No Data	1,600
Carrot	400	3.1	12	No Data	0.25	3.4	No Data	0.0032	0.0006	No Data	3,100	17,000	No Data	2,600
Onion (bulb)	320	1.5	5	No Data	0.25	3.4	No Data	0.0012	0.00023	No Data	8,100	43,000	No Data	6,800
Leek	320	2.3	7	No Data	0.25	3.4	No Data	0.0019	0.00036	No Data	5,300	28,000	No Data	4,400
Onion (bunching)	1,200	0.86	10	No Data	0.25	3.4	No Data	0.0027	0.0005	No Data	3,800	20,000	No Data	3,200
Lettuce (head)	320	24	77	No Data	0.25	3.4	No Data	0.02	0.0037	No Data	510	2,700	No Data	430
Lettuce (leaf)	320	23	74	No Data	0.25	3.4	No Data	0.019	0.0036	No Data	530	2,800	No Data	440
Spinach	1,200	0.51	6	No Data	0.25	3.4	No Data	0.0016	0.0003	No Data	6,400	34,000	No Data	5,300
Squash (winter)	320	0.23	1	No Data	0.25	3.4	No Data	0.00019	0.000036	No Data	53,000	280,000	No Data	44,000
Squash (summer)	480	0.23	1	No Data	0.25	3.4	No Data	0.00028	0.000054	No Data	35,000	190,000	No Data	30,000
Melon	240	1.5	5	No Data	0.25	3.4	No Data	0.00093	0.00017	No Data	11,000	57,000	No Data	9,100
Cucumber	400	1.3	5	No Data	0.25	3.4	No Data	0.0013	0.00025	No Data	7,500	40,000	No Data	6,300
Tomato	160	1.1	1.76	No Data	0.25	3.4	No Data	0.00045	0.000085	No Data	22,000	120,000	No Data	19,000
Pepper (bell, non-bell)	240	2.5	6	No Data	0.25	3.4	No Data	0.0015	0.00029	No Data	6,500	34,000	No Data	5,500
Cabbage	120	12	19	No Data	0.25	3.4	No Data	0.0037	0.0007	No Data	2,700	14,000	No Data	2,300
Broccoli	160	12	19	No Data	0.25	3.4	No Data	0.0049	0.00093	No Data	2,000	11,000	No Data	1,700
Mustard green	400	1.7	7	No Data	0.25	3.4	No Data	0.0017	0.00033	No Data	5,700	30,000	No Data	4,800
Barley	19,000	0.023	4	No Data	0.25	3.4	No Data	0.0011	0.00021	No Data	8,900	47,000	No Data	7,500
Buckwheat	4,000	0.023	1	No Data	0.25	3.4	No Data	0.00024	0.000045	No Data	42,000	220,000	No Data	36,000
Corn (field and popcorn), Teosinte	3,000	0.023	1	No Data	0.25	3.4	No Data	0.00018	0.000034	No Data	56,000	300,000	No Data	47,000

Table A.4.5. Short-Term Secondary Handler (Planter) Seed Treatment Exposure and Risks.

Crop	Lbs seed treated or planted/day ^a	App. Rate ^b (lb ai/100 lb)	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f}			Dose ^{g,h} (mg/kg/day)			MOE ^{i,j,k,l} (Target = 100)				
				Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Rye	22,000	0.023	5	No Data	0.25	3.4	No Data	0.0013	0.00025	No Data	7,700	41,000	No Data	6,500
Sorghum	800	0.023	0.18	No Data	0.25	3.4	No Data	0.000047	0.0000089	No Data	210,000	1,100,000	No Data	180,000
Triticale	20,000	0.023	5	No Data	0.25	3.4	No Data	0.0012	0.00022	No Data	8,500	45,000	No Data	7,100
Wheat	30,000	0.023	7	No Data	0.25	3.4	No Data	0.0018	0.00034	No Data	5,600	30,000	No Data	4,700
Potato Seed Pieces	100,000	0.0041	4	No Data	0.25	3.4	No Data	0.0011	0.0002	No Data	9,500	50,000	No Data	8,000

- a. HED default for lb seed planted per day from HED ExpoSAC Policy # 15 and information obtained from industry.
- b. Application Rates based on proposed uses on label for imidacloprid product Sepresto 75 WS (Reg. No. 264-xxx). Application rates in oz product/1,000 seed provided on the label were converted to lb ai/100 lb seed using information on number of seeds/lb provided by the Registrant and the % active ingredient in the product.
- c. Unit exposures for planters from HED ExpoSAC Policy 14: Standard Operating Procedures for Seed Treatment.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.
- e. SL w/gloves: Baseline plus chemical-resistant gloves.
- f. Baseline Inhalation: No respirator.
- g. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x dermal-absorption factor (7.2%) / body weight (70 kg).
- h. Inhalation Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x conversion factor (1 mg/1,000 µg) / body weight (70 kg).
- i. Dermal MOE = NOAEL (10 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.
- j. Inhalation MOE = NOAEL (10 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.
- k. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).
- l. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).

Table A.4.6. Intermediate-Term Secondary Handler (Planter) Seed Treatment Exposure and Risks.

Crop	Lbs seed treated or planted/day ^a	App. Rate ^b (lb ai/100 lb)	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f}			Dose ^{g,h} (mg/kg/day)			MOE ^{i,j,k,l} (Target = 100)				
				Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Radish	1,600	1.3	21	No Data	0.25	3.4	No Data	0.0053	0.001	No Data	1,700	9,200	No Data	1,500
Carrot	400	3.1	12	No Data	0.25	3.4	No Data	0.0032	0.0006	No Data	2,900	15,000	No Data	2,500
Onion (bulb)	320	1.5	5	No Data	0.25	3.4	No Data	0.0012	0.00023	No Data	7,500	40,000	No Data	6,300
Leek	320	2.3	7	No Data	0.25	3.4	No Data	0.0019	0.00036	No Data	4,900	26,000	No Data	4,100
Onion (bunching)	1,200	0.86	10	No Data	0.25	3.4	No Data	0.0027	0.0005	No Data	3,500	19,000	No Data	2,900
Lettuce (head)	320	24	77	No Data	0.25	3.4	No Data	0.02	0.0037	No Data	470	2,500	No Data	400
Lettuce (leaf)	320	23	74	No Data	0.25	3.4	No Data	0.019	0.0036	No Data	490	2,600	No Data	410
Spinach	1,200	0.51	6	No Data	0.25	3.4	No Data	0.0016	0.0003	No Data	5,900	31,000	No Data	5,000
Squash (winter)	320	0.23	1	No Data	0.25	3.4	No Data	0.00019	0.000036	No Data	49,000	260,000	No Data	41,000
Squash (summer)	480	0.23	1	No Data	0.25	3.4	No Data	0.00028	0.000054	No Data	33,000	170,000	No Data	28,000
Melon	240	1.5	5	No Data	0.25	3.4	No Data	0.00093	0.00017	No Data	10,000	53,000	No Data	8,500
Cucumber	400	1.3	5	No Data	0.25	3.4	No Data	0.0013	0.00025	No Data	7,000	37,000	No Data	5,900
Tomato	160	1.1	1.76	No Data	0.25	3.4	No Data	0.00045	0.000085	No Data	21,000	110,000	No Data	17,000
Pepper (bell, non-bell)	240	2.5	6	No Data	0.25	3.4	No Data	0.0015	0.00029	No Data	6,000	32,000	No Data	5,100
Cabbage	120	12	19	No Data	0.25	3.4	No Data	0.0037	0.0007	No Data	2,500	13,000	No Data	2,100
Broccoli	160	12	19	No Data	0.25	3.4	No Data	0.0049	0.00093	No Data	1,900	10,000	No Data	1,600
Mustard green	400	1.7	7	No Data	0.25	3.4	No Data	0.0017	0.00033	No Data	5,300	28,000	No Data	4,500
Barley	19,000	0.023	4	No Data	0.25	3.4	No Data	0.0011	0.00021	No Data	8,300	44,000	No Data	7,000
Buckwheat	4,000	0.023	1	No Data	0.25	3.4	No Data	0.00024	0.000045	No Data	39,000	210,000	No Data	33,000
Corn (field and popcorn), Teosinte	3,000	0.023	1	No Data	0.25	3.4	No Data	0.00018	0.000034	No Data	52,000	280,000	No Data	44,000

Table A.4.6. Intermediate-Term Secondary Handler (Planter) Seed Treatment Exposure and Risks.

Crop	Lbs seed treated or planted/day ^a	App. Rate ^b (lb ai/100 lb)	Amount Handled per day (lb ai/day)	Unit Exposure ^{c,d,e,f}			Dose ^{g,h} (mg/kg/day)			MOE ^{i,j,k,l} (Target = 100)				
				Baseline Dermal (mg/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Baseline Dermal	SL w/gloves Dermal	Baseline Inhalation	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Rye	22,000	0.023	5	No Data	0.25	3.4	No Data	0.0013	0.00025	No Data	7,100	38,000	No Data	6,000
Sorghum	800	0.023	0.18	No Data	0.25	3.4	No Data	0.000047	0.0000089	No Data	200,000	1,000,000	No Data	170,000
Triticale	20,000	0.023	5	No Data	0.25	3.4	No Data	0.0012	0.00022	No Data	7,900	42,000	No Data	6,600
Wheat	30,000	0.023	7	No Data	0.25	3.4	No Data	0.0018	0.00034	No Data	5,200	28,000	No Data	4,400
Potato seed pieces	100,000	0.0041	4	No Data	0.25	3.4	No Data	0.0011	0.0002	No Data	8,800	47,000	No Data	7,400

- a. HED default for lb seed planted per day from HED ExpoSAC Policy # 15 and information obtained from industry.
- b. Application Rates based on proposed uses on label for imidacloprid product Sepresto 75 WS (Reg. No. 264-xxx). Application rates in oz product/1,000 seed provided on the label were converted to lb ai/100 lb seed using information on number of seeds/lb provided by the Registrant and the % active ingredient in the product.
- c. Unit exposures for planters from HED ExpoSAC Policy 14: Standard Operating Procedures for Seed Treatment.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.
- e. SL w/gloves: Baseline plus chemical-resistant gloves.
- f. Baseline Inhalation: No respirator.
- g. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x dermal-absorption factor (7.2%) / body weight (70 kg).
- h. Inhalation Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/lb seed) x amount treated (lb seed/day) x conversion factor (1 mg/1,000 µg) / body weight (70 kg).
- i. Dermal MOE = NOAEL (9.3 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.
- j. Inhalation MOE = NOAEL (9.3 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.
- k. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).
- l. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).

Table A.4.7. Short-Term Occupational Handler Exposure and Risk for Soil-Directed Uses.

Exposure Scenario	Crop	App. Rate ^a (lb ai/A)	Area Treated Daily ^b (acres)	Unit Exposure ^{c,d,e}			Dose ^{f,g} (mg/kg/day)			MOEs ^{h,i,j,k}				
				Baseline Dermal (mg/lb ai)	Baseline Inhalation (ug/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Dermal	Baseline Inhalation	SL w/gloves Dermal	Baseline Dermal	Baseline Inhalation	SL w/gloves Dermal	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Mixer/Loader														
Mixing/Loading Liquids for Chemigation Applications	Bulb vegetables	0.5	350	2.9	1.2	0.023	0.52	0.003	0.0041	19	3,300	2,400	19	1,400
Mixing/Loading Liquids for Groundboom Applications	Bulb vegetables	0.5	80	2.9	1.2	0.023	0.12	0.00069	0.00095	84	15,000	11,000	83	6,100
Applicator														
Applying Sprays via Groundboom Equipment	Bulb vegetables	0.5	80	0.014	0.74	0.014	0.00058	0.00042	0.00058	17,000	24,000	17,000	10,000	10,000
Mixer/Loader/Applicator														
Mixing/Loading/ Applying Liquids with Low-Pressure Handwand (PHED)	Bulb vegetables	0.5	5	100	30	0.43	0.26	0.0011	0.0011	39	9,300	9,000	39	4,600
Mixing/Loading/ Applying Liquids with Low-Pressure Handwand (ORETF)	Bulb vegetables	0.5	5	15	2.7	0.33	0.039	0.000096	0.00085	260	100,000	12,000	260	11,000
Mixing/Loading/ Applying Liquids with a Handgun Sprayer (LCO ORETF data)	Bulb vegetables	0.5	5	No Data	1.8	0.45	No Data	0.000064	0.0012	No Data	160,000	8,600	No Data	8,200

a. Application Rates based on proposed use on label for imidacloprid product Gaucho[®] 550 SC Insecticide (Reg. No. 264-827)

b. ExpoSAC Policy # 9.1

c. Unit Exposures based on PHED Version 1.1.

d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves; Baseline Inhalation: no respirator.

e. SL w/gloves: Baseline plus chemical-resistant gloves.

f. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/acre) x acres treated x dermal-absorption factor (7.2%) / body weight (70 kg).

g. Inhalation Dose (mg/kg/day) daily unit exposure (ug/lb ai) x application rate (lb ai/acre) x acres treated x inhalation absorption (100%) x conversion factor (1 mg/1,000 ug) / body weight (70 kg).

h. Dermal MOE = NOAEL (10 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.

i. Inhalation MOE = NOAEL (10 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.

j. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).

k. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).

Table A.4.8. Intermediate-Term Occupational Handler Exposure and Risk for Soil-Directed Uses.

Exposure Scenario	Crop	App. Rate ^a (lb ai/A)	Area Treated Daily ^b (acres)	Unit Exposure ^{c,d,e}			Dose ^{f,g} (mg/kg/day)			MOEs ^{h,i,j,k}				
				Baseline Dermal (mg/lb ai)	Baseline Inhalation (ug/lb ai)	SL w/gloves Dermal (mg/lb ai)	Baseline Dermal	Baseline Inhalation	SL w/gloves Dermal	Baseline Dermal	Baseline Inhalation	SL w/gloves Dermal	Combined Baseline Dermal + Baseline Inhalation	Combined SL w/gloves Dermal + Baseline Inhalation
Mixer/Loader														
Mixing/Loading Liquid Concentrates for Chemigation Applications	Bulb vegetables	0.5	350	2.9	1.2	0.023	0.52	0.003	0.0041	18	3,100	2,200	18	1,300
Mixing/Loading Liquids Concentrates for Groundboom Applications	Bulb vegetables	0.5	80	2.9	1.2	0.023	0.12	0.00069	0.00095	78	14,000	9,800	78	5,700
Applicator														
Applying Sprays via Groundboom Equipment	Bulb vegetables	0.5	80	0.014	0.74	0.014	0.00058	0.00042	0.00058	16,000	22,000	16,000	9,300	9,300
Mixer/Loader/Applicator														
Mixing/Loading/Applying Liquid Concentrates with Low-Pressure Handwand (PHED)	Bulb vegetables	0.5	5	100	30	0.43	0.26	0.0011	0.0011	36	8,700	8,400	36	4,300
Mixing/Loading/Applying Liquid Concentrates with Low-Pressure Handwand (ORETF)	Bulb vegetables	0.5	5	15	2.7	0.33	0.039	0.000096	0.00085	240	96,000	11,000	240	9,800
Mixing/Loading/Applying Liquid Concentrates with a Handgun Sprayer (LCO ORETF data)	Bulb vegetables	0.5	5	No Data	1.8	0.45	No Data	0.000064	0.0012	No Data	140,000	8,000	No Data	7,600

- a. Application Rates based on proposed use on label for imidacloprid product Gaucho[®] 550 SC Insecticide (Reg. No. 264-827)
- b. ExpoSAC Policy # 9.1
- c. Unit Exposures based on PHED Version 1.1.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves; Baseline Inhalation: no respirator.
- e. SL w/gloves: Baseline plus chemical-resistant gloves.
- f. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/acre) x acres treated x dermal-absorption factor (7.2%) / body weight (70 kg).
- g. Inhalation Dose (mg/kg/day) = daily unit exposure (ug/lb ai) x application rate (lb ai/acre) x acres treated x inhalation absorption (100%) x conversion factor (1 mg/1,000 ug) / body weight (70 kg).
- h. Dermal MOE = NOAEL (9.3 mg/kg/day) / dermal daily dose (mg/kg/day). Level of concern = 100.
- i. Inhalation MOE = NOAEL (9.3 mg/kg/day) / inhalation daily dose (mg/kg/day). Level of concern = 100.
- j. Combined Baseline Dermal + Inhalation MOE = NOAEL (mg/kg/day) / (Baseline Dermal dose + Baseline Inhalation dose).

i. Combined SL w/gloves Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (SL w/gloves Dermal dose + Baseline Inhalation dose).

Table A.4.9. Short- and Intermediate-Term Occupational Handler Exposure and Risk for Crack and Crevice Use

Application Rate ^a	Area Treated Daily ^b	Unit Exposures (mg/lb ai) ^c			Dose (mg/kg/day) ^{f,g}		MOE ^{h,i}		
		Baseline Dermal ^d	Baseline Inhalation ^d	PPE-G Dermal ^e	Baseline Inhalation	PPE-G Dermal	Baseline Inhalation	PPE-G Dermal	PPE-G Dermal + Baseline Inhalation
SHORT-TERM									
Mixing/Loading/Applying Wettable Powders with Low-Pressure Handwand (PHED)									
0.008 lb ai/gal	40 gallons	No Data	1.1	8.6	0.005	0.0028	2,000	3,500	1,300
INTERMEDIATE-TERM									
Mixing/Loading/Applying Wettable Powders with Low-Pressure Handwand (PHED)									
0.008 lb ai/gal	40 gallons	No Data	1.1	8.6	0.005	0.0028	1,800	3,300	1,200

- a. Application Rates based on proposed use on label for imidacloprid product Temprid™ SC Insecticide (Reg. No. 432-1483)
- b. Science Advisory Council Policy # 9.1
- c. Unit Exposures based on PHED Version 1.1.
- d. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves; Baseline Inhalation: no respirator.
- e. PPE-G Dermal: Baseline plus chemical-resistant gloves.
- f. Dermal Dose (mg/kg/day) = daily unit exposure (mg/lb ai) * application rate (lb ai/gallon) * amount handled (gallons) * dermal absorption factor (7.2%) / body weight (70 kg).
- g. Inhalation Dose (mg/kg/day) = daily unit exposure (mg/lb ai) * application rate (lb ai/gallon) * amount handled (gallons) * inhalation absorption (100%) / body weight (70 kg).
- h. MOE = NOAEL (short-term = 10 mg/kg/day; intermediate-term = 9.3 mg/kg/day) / daily dose (mg/kg/day). Level of concern = 100.
- i. PPE-G Dermal + Baseline Inhalation MOE = NOAEL (mg/kg/day) / (PPE-G Dermal dose + Baseline Inhalation dose).



13544

R181434

Chemical Name: Imidacloprid

PC Code: 129099
HED File Code: 14000 Risk Reviews
Memo Date: 3/16/2010
File ID: 00000000
Accession #: 000-00-0134

HED Records Reference Center
3/18/2010