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HUMAN HEALTH RISK ASSESSMENT

Azinphos-Methyl

May 19, 1999

U.S. EPA
Office of Pesticide Programs
Health Effects Division (7509C)

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I. EXECUTIVE SUMMARY

The Health Effects Division (HED) has evaluated the azinphos methyl database and determined that the data are adequate to support reregistration. The toxicological database is adequate to support reregistration. Residue chemistry requirements are substantially complete pending residue field trial data for walnuts and cotton gin byproducts.

Azinphos methyl is an organophosphate pesticide. The toxicology database provides clear, strong evidence confirming that azinphos methyl has anticholinesterase activity in various species including dogs, rabbits, rats, mice and hens. In acute toxicity studies, azinphos methyl exhibits low to high toxicity depending on the route of administration and the species used. It is acutely toxic at relatively low oral or dermal doses when tested in rats, but was found to be less toxic in rabbits exposed dermally because it is detoxified in the rabbit's skin. Toxic signs observed in animals treated acutely with azinphos methyl are consistent with cholinesterase inhibition and are typical of the acute toxic signs induced by other organophosphate chemicals. They include: tremors, convulsions salivation, and dyspnea (labored breathing). Inhibition of plasma, erythrocyte (red blood cell)and brain cholinesterase (ChE) activity is directly dose-related and occurs by all routes of exposure and following exposure for various durations. There is no indication of an increased susceptibility of the fetuses or offspring of rats or rabbits after pre-natal and/or postnatal exposure to azinphos methyl. In all studies examined, maternal or parental no observed adverse effect levels (NOAELs) are lower or equivalent to the developmental offspring NOAELs. Azinphos methyl has been classified in "Group E" (i.e., the chemical is characterized as "Not Likely" to be carcinogenic in humans via relevant routes of exposure) because there is no evidence that azinphos methyl altered the spontaneous tumor profile in rats or mice. Based on metabolism studies in rats, azinphos methyl is degraded and/or eliminated within 72 hours post-dosing and does not accumulate in tissues. The metabolism of azinphos methyl in rats proceeds largely through the action of glutathione-S-transferase and mixed function oxidases. There were no major sex- or dose-related differences in the disposition or metabolism of azinphos methyl. The FQPA Safety Factor Assessment Review Committee (the Committee) determined that the FQPA safety factor for increased susceptibility to infants and children should be removed for azinphos methyl.

Five exposure and risk assessments were conducted for azinphos methyl: acute dietary, chronic dietary, non-dietary short- and intermediate-term dermal, and non-dietary inhalation (for any time period). The acute and chronic dietary assessments capture exposure estimates for the general public. The latter three assessments are for occupational exposures. The five different assessments were conducted separately based on cholinesterase inhibition.

For the acute dietary exposure and risk assessment, the toxic endpoint selected was the lowest observed adverse effect level (LOAEL) based on plasma, erythrocyte, and brain cholinesterase inhibition from an acute neurotoxicity study in rats (1.0 mg/kg/day). The LOAEL was selected because the no observed adverse effect level (NOAEL) was not established in the study. The uncertainty factor used in this assessment was 300, which included a 10X for interspecies extrapolation, a 10X for intraspecies variation, and a 3X for the lack of a NOAEL in a critical study. The resultant acute RfD for dietary assessment is 0.003 mg/kg/day.

For the chronic dietary exposure and risk assessment, the toxic endpoint selected was the NOAEL of 0.149 mg/kg/day based on erythrocyte cholinesterase inhibition at a LOAEL of 0.688 mg/kg/day from a 1-year chronic toxicity study in dogs. The uncertainty factor used in this assessment was 100 and resulted in a chronic RfD for dietary assessment of 0.00149 mg/kg/day.

For the short-term dermal exposure and risk assessments the toxic endpoint selected was based on erythrocyte cholinesterase inhibition from a dermal absorption study in rats (NOAEL = 0.56 mg/kg/day and LOAEL = 5.6 mg/kg/day). Because the endpoint selected for short-term risk assessment was based on a study using dermal doses of azinphos methyl, no correction for percent of azinphos methyl absorbed through the skin was necessary. For intermediate-term dermal exposure and risk assessments, the aforementioned NOAEL from the 1-year chronic feeding study in dogs was selected (0.149 mg/kg/day). Because the endpoint selected for intermediate-term risk assessment was based on a study using oral doses of azinphos methyl, a dermal absorption factor of 41.7% was applied to the NOAEL selected for the intermediate-term assessment, resulting in an equivalent dermal dose of 0.36 mg/kg/day. For inhalation exposure (any time period), the endpoint selected was a NOAEL (0.0012 mg/L) based on inhibition of plasma and erythrocyte cholinesterase at a LOAEL of 0.0047 mg/L from a 90-day inhalation toxicity study. An uncertainty factor of 100 was used for all of the occupational (non-dietary) exposure assessments.

Risk Characterization

In this document, risk estimates are expressed as either a percentage of a reference dose (acute or chronic RfD) or as a margin of exposure (MOE). For the purposes of this risk assessment, risk estimates greater than 100% of the RfD (acute or chronic), and MOEs less than 300 for acute dietary exposures and less than 100 for occupational exposures exceed HED's levels of concern. Risk estimates for chronic dietary exposures will always be expressed as a percentage of the chronic RfD. The results of the revised, probabilistic analysis of acute dietary risk are presented in this summary. Results of the entire tiered assessment for acute dietary exposure and risk are provided in the body of this document under the section for Dietary Risk.

Acute Dietary Risk (Food)

Probabilistic Assessment (Tier 3). The revised acute dietary risk assessment presented in this document (the results of which are provided below) utilizes residue monitoring data available from USDA's Pesticide Data Program (PDP) and FDA's Surveillance Monitoring Program Market Basket Survey that were adjusted to reflect residues that could be potentially present in single-serving sizes of commodities. Current policy is to utilize both FDA's (Market Basket Survey) and USDA's (PDP) monitoring data when conducting chronic dietary risk assessments, only. However, a statistical model has been devised whereby we can use composite samples in an acute probabilistic dietary assessment. The results of an analysis utilizing "decomposited"

PDP and FDA residue monitoring data in a probabilistic acute dietary assessment are provided below and compared to the most recent probabilistic acute dietary analysis submitted by the registrant.

Probabilistic Acute Dietary Analysis Results at the 99.9th Percentile of Exposure					
Population Subgroup	**Bayer Analysis**		**HED Analysis**		
	Exposure	**MOE[1]**	**Exposure**	**MOE[1]**	**%aRfD[2]**
US population	0.005062	197	0.001781	561	59%
All infants (<1 year)	0.00841	118	0.003003	332	100%
Nursing infants (<1 year)	0.008483	117	0.003632	275	121%
Non-nursing infants (<1 year)	0.008336	119	0.002234	447	74%
Children (1-6 years)	0.008943	111	0.003913	255	130%
Children (7-12 years)	0.006206	161	0.002704	369	90%
[1]The Margin of Exposure (MOE) considered to be above HED's level of concern is 300 for acute dietary exposure and risk estimates. [2]The acute RfD used is 0.003 mg/kg/day.					

Based on HED's analysis, which HED believes provides the most refined assessment to date, risk estimates exceed HED's levels of concern for two subgroups at the 99.9th percentile of exposure: nursing infants less than 1 year old, and children 1 to 6 years of age. The risk estimates for these two subgroups are 121% and 130% of the acute RfD, respectively, as shown above. Risk estimates for all other subgroups are equal to or below 100% of the acute RfD and therefore below HED's level of concern. Risk estimates at the 99th percentile of exposure are below HED's level of concern for all population subgroups.

HED is also performing a critical exposure contribution analysis to determine if there was any individual with excessive consumption patterns that would affect the risk estimates. This analysis has not been completed.

USDA's PDP was created in 1991 to collect data on pesticide residues in foods. PDP monitoring data was specifically designed for use in dietary risk assessment. PDP's sampling procedures are statistically apportioned according to State population. The samples are collected at terminal markets and warehouse distribution centers which are closer to the supermarket, and eventual consumption, than the farmgate. PDP's analytical laboratory procedures emphasizes searching for PDP-required pesticide residues at the lowest possible limits of detection. Their QA/QC (quality assurance/quality control) protocols, which are based on the Agency's Good Laboratory Practices (GLPs), are designed to ensure the reliability of PDP monitoring data. PDP samples are composited samples, i.e., approximately five pounds of the commodity are chopped and blended together from which the analytical sample is taken. Analytical results from these composited samples can be used by EPA in chronic dietary risk assessment, as the residues present in a composited sample are averaged across the sample and are highly reflective of the residues consumed on an average basis.

Because of the composited samples, use of PDP monitoring data directly in an acute (one-day, high-end exposure) dietary assessment is not appropriate. Analyses of single-serving commodities, such as a single apple or potato, represent the highest concentrations that could be found in one serving of a commodity. It is these potentially high residues that are of concern for acute dietary risk assessments. Until now, EPA has used PDP monitoring data in acute dietary assessments only for blended commodities, such as apple sauce. Because of the blending that occurs when batches of apple sauce are made, use of average residues is appropriate.

However, recently Agency statisticians have developed a method using standard statistical procedures to adjust the composited residues to reflect residues that could be present, potentially, in single-serving sizes of commodities. The methodology assumes the following:
1) the weight of the sample that was composited based on PDP Standard Operating Procedures on the amount of sample collected, 2) the number of units (such as apples or oranges) in the sample that was composited, and 3) the distribution of residues in the units is lognormal. There is some data to justify the use of assumption #3. This method yields a distribution of theoretical single-serving residues (based on the composited residues) that would have resulted if the residue analysis had been done on single-serving items without compositing. Currently, this method is being applied to several of the acute dietary assessments for the first 9 organophosphates (OPs), but will require additional peer review and validation before it can be used routinely in acute dietary assessments. The Agency has conducted a paper peer review in which three nationally known statisticians have reviewed the methodology as well as responded to questions posed by the Agency. The Agency also plans to present this methodology to the Scientific Advisory Panel in May 1999.

For this analysis, PDP data for residues of azinphos methyl on individual "single servings" of pears were available. These data were used for pears, and translated directly to apples, quinces, and crabapples in the acute dietary analysis. PDP data were available and decomposited for residues of azinphos methyl on composited samples of peaches, only. Decomposited residue data on peaches were then translated to other stone fruits (i.e., plums). For other crops included in the dietary assessment, but without PDP data, existing PDP data were translated to appropriate crops within a crop grouping, i.e., PDP data for oranges were translated to other citrus crops, PDP data on spinach was translated to other leafy vegetables and the subgrouping of Brassica, and FDA data were used for all berry crops included in the dietary analysis, except for cranberries. Field trial data were used for the remaining crops. The data source used for each crop, i.e., PDP, FDA or field trial, is provided in Table 5 of Attachment 1 (HED memorandum, F. Fort, 5/12/99, D255395).

Chronic Dietary Risk (Food)

The risk estimate for chronic dietary exposure from the registered uses of azinphos methyl, does not exceed HED's level of concern. The chronic dietary exposure analysis estimates that existing uses result in an anticipated residue concentration (ARC) which represents 13% of the RfD for the U.S. general population. The subgroup with the highest exposure, Non-Nursing Infants (<1 year old), occupies 54% of the RfD, and the subgroup Children (1-6 years old) occupies 33% of the RfD. This analysis used percent crop-treated data and anticipated residues based on field trials and FDA monitoring data.

Dietary Risk (Drinking Water)

Currently, HED uses drinking water levels of comparison (DWLOCs) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). A DWLOC may vary with drinking water consumption patterns and body weights for specific subpopulations.

Because the acute exposure to residues of azinphos methyl from food alone exceeds HED's level of concern for the infants and children subgroups at the most refined levels of analysis, any exposure to azinphos methyl in drinking water would only add to a dietary exposure that already exceeds HED's levels of concern. Effectively, until the exposure to azinphos methyl from food is reduced, the DWLOC for acute exposure to azinphos methyl in drinking water is zero. Indications from both conservative model estimates and limited ground water monitoring data indicate that azinphos methyl may reach surface and ground water. Specific data on azinphos methyl in drinking water are not available for comparison with the model estimates and limited ground water monitoring data.

Based on the estimates of the average concentration of azinphos methyl in ground and surface water used in this analysis, the chronic exposure from azinphos methyl in the diet and in drinking water from registered uses of azinphos methyl, is not of concern. All concentration estimates of azinphos methyl in surface water from all use scenarios modeled indicate that chronic exposure from azinphos methyl in drinking water from registered uses of azinphos methyl, is not of concern, with the exception of a worst-case, cotton-use-scenario using maximum label rates. Based on the upper-bound concentration estimate (13.4 ppb) of azinphos methyl in surface water from this specific use, there may be a potential concern. However, the registrant has submitted labels that reduce the number of applications on cotton to four. The drinking water risk assessment can be refined to reflect the lowered rates. It is anticipated that this label change on cotton will reduce any potential risk estimate based on the existing label rates on cotton.

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Limited ground water monitoring data and model estimates from the SCI-GROW ground water model and PRZM/EXAMS surface water model were available to update this risk assessment. There are limited data from one study report suggesting that azinphos methyl can reach ground water if used in areas with karst terrain. Specifically, the Environmental Fate and Effects Division (EFED) reports detections of azinphos methyl could reach approximately 75 ppb in ground water in an area underlain by karst terrain (See EFED RED chapter), and model estimates from SCI-GROW for azinphos methyl in ground water of 0.44 ppb. Model estimates from PRZM/EXAMS for the highest peak and average concentrations of azinphos methyl in surface water were 88 ppb and 13.4 ppb, respectively, based on worst-case scenarios for cotton uses at the maximum label rates. The registrant intends to initiate a drinking water sampling program for azinphos methyl to address drinking water concerns posed by model estimates and limited monitoring data.

Based on its physical-chemical properties, residues of azinphos methyl are not expected to persist long enough in either ground- or surface-water-sourced drinking water to pose a chronic exposure scenario of concern; however, additional monitoring data on drinking water are recommended to verify exposure suggested by the models and limited monitoring data for use in the acute exposure analysis.

Non-Occupational (Residential) Risk

There are no registered residential uses of azinphos methyl. Therefore, no exposure or risk calculations for residential uses are warranted.

Occupational Risk

Handler Risk Estimates. HED has serious concerns regarding occupational exposure and risk estimates for a number of exposure scenarios during application for pesticide handlers. Estimated baseline risks are calculated assuming minimal personal protective equipment (PPE), i.e., long pants and a long-sleeved shirt, no gloves, and an open cab or tractor). A second risk estimate considers the use of additional PPE, which includes a double layer of clothing and gloves. A third risk estimate considers the use of engineering controls (closed application and mixing systems, and water soluble packets). For dermal short-term and intermediate-term exposures using baseline protection, risk estimates exceeded HED's levels of concern for all of the 14 major applicator/handler scenarios. Risk estimates continued to exceed HED's levels of concern using additional PPE, for the 14 major scenarios. Using engineering controls, MOEs for short-term dermal exposure were >100 for 3 out of 14 major scenarios for which engineering controls were applicable (engineering controls are applicable for 11 out of 14 scenarios). However, only two of these exposure scenarios has MOEs >100 for intermediate-term exposures. And of these two scenarios with MOEs >100 for intermediate exposures, the risk estimate for 1(c) was based on an application rate less than the labeled maximum rate, and the other (10) is for an exposure scenario for flaggers that has been prohibited on the

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currently-approved labels. Effectively, this still leaves 13 out of 14 occupational exposure scenarios (for both short- and intermediate-term exposures) for which MOEs are less than 100 at all application rates. These 13 exposure scenarios exceed HED's level of concern despite maximum mitigation measures. Note that when exposure scenarios (9) and (10) are removed because of label prohibitions, this leaves 12 exposure scenarios, all of which exceed HED's level of concern.

For inhalation exposures (any time period) using baseline protection, risk estimates expressed as MOEs were >100 for 9 out of 14 major applicator/handler scenarios. Risk estimates improved using additional PPE with MOEs >100 for 11 out of 14 major scenarios. Using engineering controls, MOEs were >100 for all 13 out of 14 major scenarios for which engineering controls were applicable. However, this leaves 1 occupational exposure scenario (e.g., mixing/loading/applying sprays using high pressure handwands, as in greenhouses) for which the inhalation MOE is less than 100 and exceeds HED's level of concern despite maximum mitigation measures.

When inhalation and dermal risks are combined, 13 out of 14 occupational exposure scenarios produce MOEs less than 100, therefore, exceeding HED's levels of concern. In general, risk estimates for dermal exposures are an order of magnitude greater than those for inhalation exposures.

Post-Application Risk Estimates. In summary, post-application risk estimates from the use of azinphos methyl WP50 formulation on tomatoes at the maximum labeled rate (1.5 lb ai./A) result in MOEs greater than 100 at existing 2-day and 1-day restricted entry intervals (REIs), respectively. Post-applicator risk estimates for uses of the 2S formulation of azinphos methyl on potatoes at the actual maximum application rate of 0.75 lb ai/A result in MOEs <100 indicating that the existing 2-day REI is too short. Uses of the WP50 formulation on potatoes at 0.75 lb ai/A, also result in MOEs less than 100 at the existing 2-day REI and exceed HED's level of concern. Based on apple data (using both the WP and emulsifiable concentrate), post-applicator risk estimates for orchard crops were calculated for harvesting, propping, and thinning activities. MOEs calculated for propper activities were less than 100, for all application rates >1.0 lb ai/A. MOEs were less than 100 for all harvesting and thinning activities regardless of the application rates and REIs. MOE calculations were less than 100 for all post-applicator risks for citrus, grape, and berry uses of azinphos methyl at all labelled use rates and existing REIs. Data for cotton revealed MOEs less than 100 for application rates of 0.50 to 0.75 lb ai/A (maximum rate) at the existing REI of 1-day. At "typical" rates (0.25 lb ai/A) 2 out of 3 sites tested had MOEs less than 100 at the 1-day REI.

HED has serious concern for reentry workers and the post-application exposure and risk associated with all uses of azinphos methyl except its use in the WP50 formulation on tomatoes at 1.5 lb ai/A and the 2L formulation on cotton at 0.25 lb ai/A. Risks expressed as MOEs associated with harvesting and tending activities for all other analyzed crops were well below 100.

Susceptibility to Infants and Children

The FQPA Safety Factor Assessment Review Committee (the Committee) determined that the FQPA safety factor should be removed for azinphos methyl. This decision was based in part on the assessment provided to the committee by the HED Hazard Identification Assessment Review Committee (HIARC). The HIARC recommended that the FQPA Safety Factor should be removed because:

(i) Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposure in rats and rabbits.

(ii) Both a one- and a two-generation reproductive toxicity study in rats showed no increased susceptibility in pups when compared to adults.

(iii) There was no evidence of abnormalities in the development of the fetal nervous system in the pre/postnatal studies. Neither brain weight nor histopathology (nonperfused) of the nervous system was affected in the subchronic and chronic toxicity studies.

(iv) The toxicology database is complete based on current requirements and there are no data gaps. There is no evidence to require a developmental neurotoxicity study.

Available data on exposure were also considered. The toxicity database used is complete based on current requirements. The available residue data used for dietary exposure provides the most highly-refined assessment possible at this time. Limited data for use in assessing drinking water exposure were available, but the models used provide upper-bound concentration estimates of azinphos methyl in groundwater (except for karst terrain) and surface water, and are based on conservative assumptions regarding pesticide transport from the point of application to water sources, and are therefore considered health-protective.

Aggregate Exposure/Risk

Acute Aggregate Risk. The aggregate acute dietary risk includes exposures to azinphos methyl residues in food and water. However, HED notes that exposure to azinphos methyl residues in food alone exceed HED's levels of concern for acute dietary risk. At this point in time and until the exposure to azinphos methyl in the diet is reduced or a more refined risk assessment is provided, any additional exposure to azinphos methyl through drinking water would only cause acute risk estimates to further exceed HED's level of concern. In effect, the drinking water level of comparison (DWLOC) for acute effects to azinphos methyl is zero and a conservative estimate of the maximum concentration of azinphos methyl in surface water ranges from 5 to 88 ppb depending on which use rate is selected for the model simulation. In ground water, limited monitoring data of unknown quality specific to karst terrain (16 detections out of 60 samples collected in the state of Virginia from 60 wells) indicate that azinphos methyl may reach ground water at concentrations up to approximately 75 ppb. This is in excess of the DWLOC (zero) for acute aggregate exposure to azinphos methyl. Once monitoring data on azinphos methyl in drinking water are available, the drinking water risk estimate can be refined.

Chronic Aggregate Risk. The chronic aggregate risk assessment for azinphos methyl will include risk estimates associated with dietary exposure through food and water only, because azinphos methyl has no registered residential uses. Anticipated residues and percent crop-treated data for commodities with published tolerances result in an exposure to azinphos methyl through food which represents 13% of the RfD for the U.S. general population. The most highly exposed subgroup, Non-Nursing Infants (<1 year old), occupies 54% of the RfD and Children (1-6 years old) occupies 33% of the RfD.

HED has calculated drinking water levels of comparison (DWLOCs) for chronic exposure to azinphos methyl in drinking water for the following four subpopulations: the general U.S. population/Hispanics (45 ppb), females, 13-19 (39 ppb), children, 1 to 6 years old (10 ppb), and non-nursing infants, <1 year old (7 ppb). These subpopulations were selected because they contain the individuals believed to be those most highly exposed subpopulations representing males, females, children, and infants, respectively. A conservative estimate of average concentrations of azinphos methyl in ground water is 0.44 ppb and is less than HED's levels of comparison for drinking water. However, average concentration estimates of azinphos methyl in surface water from conservative models range from <1 to 13.4, ppb depending on which use rate is selected for the model simulation. For the subpopulation infants and children, the highest concentration estimate (13.4 ppb from the maximum labeled cotton use scenario) exceeds the DWLOCs calculated for chronic effects. However, as stated previously, the registrant has submitted labels with fewer applications resulting in lower use rates on cotton. It is anticipated that this label change on cotton will reduce any potential risk estimate based on the existing label rates on cotton.

Excluding cotton use at the maximum label rate, HED concludes with reasonable certainty that residues of azinphos methyl in drinking water (when considered along with exposure from food for which HED has reliable data) result in a chronic aggregate human health risk estimate that does not exceed HED's levels of concern for all subpopulations under all other use scenarios. HED bases this determination on a comparison of estimated concentrations of azinphos methyl in surface water to back-calculated "levels of comparison" for azinphos methyl in drinking water. The estimate of azinphos methyl in ground and surface water are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to ground and surface water.

Conclusion

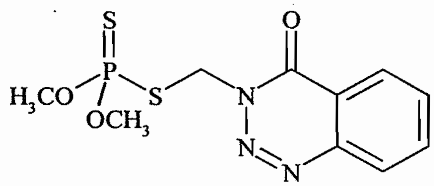
In conclusion, according to the exposure and risk assessments described here, currently registered uses of azinphos methyl result in dietary risk estimates from acute exposures through food alone that already exceed HED's level of concern, for two population subgroups: nursing infants <1 year old, and children 1 to 6 years of age. Any additional acute exposure through drinking water would worsen a risk estimate that exceeds HED's level of concern. Chronic aggregate human health risk estimates do not exceed HED's levels of concern. Risk estimates based on average concentrations of azinphos methyl in surface water as predicted from conservative water quality models based on a "high-exposure" scenario reflecting maximum label use rates of azinphos methyl on cotton do indicate a potential risk concern; however, the registrant has submitted labels with fewer applications resulting in lower use rates on cotton. Model estimates indicate that the lowered use rates on cotton should reduce any potential risk. Additional monitoring data on azinphos methyl residues in drinking water are recommended to clarify the situation. Occupational risk estimates associated with application, mixing, loading activities exceed HED's level of concern for many exposure scenarios. Risk estimates for post-application activities, such as harvesting, exceed HED's level of concern for a majority of exposure scenarios. Documented incident data on reported cases of azinphos methyl poisonings support the results of these occupational exposure and risk estimates.

II. SCIENCE ASSESSMENT

A. PHYSICAL AND CHEMICAL PROPERTIES ASSESSMENT

1. Description of Chemical

Azinphos methyl [O,O-dimethyl-S-((4-oxo-1,2,3-benzotriazin-3(4H)-yl)methyl)phosphorodithioate] is an insecticide used for control of pests on various fruits, melons, nuts, vegetables, field crops, ornamentals, and shade trees.



Empirical Formula:	$C_{10}H_{12}N_3O_3PS_2$
Molecular Weight:	317.1
CAS Registry No.:	86-50-0
Pesticide Chemical No.:	058001

2. Identification of Active Ingredients

Pure azinphos methyl is a colorless to white odorless crystalline solid with a melting point of 72-74° C. Technical azinphos methyl (T) is a cream to yellow-brown granular solid with a melting point of 67-70° C. Azinphos methyl is readily soluble in most organic solvents (acetone, toluene, chloroform, acetonitrile, benzene, xylene, carbon tetrachloride, and chlorobenzene), slightly soluble in methanol, ethanol, and 1-propanol, and nearly insoluble in water (28 ppm at 20° C). Azinphos methyl is subject to hydrolysis and decomposes with gas evolution at elevated temperatures.

3. Manufacturing Use Products

A search of the Reference Files System (REFS) conducted 12/10/96 identified five azinphos methyl manufacturing-use products (MPs) registered under Shaughnessy No. 058001. The registered azinphos methyl MPs are listed in Table 1; only these products are subject to a reregistration eligibility decision.

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Table 1. Registered Azinphos Methyl Manufacturing-use Products		
Formulation	**EPA Reg. No.**	**Registrant**
94% T	10163-95	Gowan Company
85% T	11678-4	Makhteshim Chemical Works, Ltd.
85% FI	11678-53	
85% T [1]	3125-108	Bayer Corporation [2]
85% FI[3]	3125-425	

[1]The Reference Files System (REFS) currently identifies this product as a formulation intermediate; however, it has been correctly identified in previous Agency reviews as a technical product.

[2]Formerly Mobay Corporation.

[3]This product has been cancelled.

4. Regulatory Background

The Azinphos methyl Registration Standard dated 4/4/86 and Guidance Document dated 9/11/86 required additional generic and product-specific product chemistry data for the registered MPs. In response, updated data were submitted for the Makhteshim and Bayer 85% technical products (Ts). The Azinphos methyl Reregistration Standard Update dated 1/8/91 reviewed submitted data and summarized the product chemistry database. The update required additional data concerning GLNs 62-1, 62-2, 62-3, and 63-13 (OPPTS 830.1700, 830.1750, 830.1800, and 830.6313) for the Makhteshim 85% T (EPA Reg. No. 11678-4); and additional data concerning GLNs 62-1 and 62-2 (OPPTS 830.1700 and 830.1750) for the Bayer 85% T (EPA Reg. No. 3125-108). These data with the exception of data for 830.6313 were submitted and reviewed (MRID's 41873601, 41521401, 44121301, 44121302, and 44121303). All product chemistry data were required for the Gowan 94% T (EPA Reg. No. 10163-95).

The Makhteshim and Bayer 85% formulation intermediates (FIs) (EPA Reg. Nos. 3125-425 and 11678-53) were not registered until after the Update was issued, and data pertaining to reregistration have not been submitted for these products. HED has determined, based on comparison of the CSFs, that the composition of the Makhteshim 85% FI is identical to the composition of the Makhteshim 85% T; thus, the product should be identified as a technical product, and data requirements for the 85% FI will be fulfilled by data submitted for the 85% T. Examination of the CSF for the Bayer 85% FI suggests that this product should be identified as a technical product.

The current status of the product chemistry data requirements for the azinphos methyl products is presented in the data summary tables attached in Appendix I. Refer to these tables for a listing of the outstanding product chemistry data requirements.

5. Conclusions

All pertinent data requirements are not satisfied for the azinphos methyl MPs. Additional data required for the Makhteshim 85% T and 85% FI (OPPTS 830.1750, 830.6313, and 830.7050) have been submitted and are in review. For the Bayer 85% T, the following data are required: OPPTS 830.1750 and 830.7050. All product chemistry data remain outstanding for the Gowan 94% T and the Bayer 85% FI. Provided that:

- The registrants submit the data required in the attached data summary tables for the 94% T, 85% Ts, and 85% FIs, and

- Either certify that the suppliers of beginning materials and the manufacturing processes for the azinphos methyl MPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages,

then the product chemistry data requirements will be complete.

B. HUMAN HEALTH RISK ASSESSMENT

1. Hazard Identification

On September 16, 1993, the Health Effects Division's (HED's) RfD/Peer Review Committee established a Reference Dose of 0.00149 mg/kg/day based on a NOAEL of 0.149 mg/kg/day established in a chronic toxicity study in dogs and an Uncertainty Factor (UF) of 100 for inter-species extrapolation and intra-species variation (Memorandum: G. Ghali, HED to L. Rossi, RD, Dated 12/07/93).

On February 27, 1997, the HED's Toxicology Endpoint Selection (TES) Committee selected the doses and endpoints for acute dietary as well as occupational and residential exposure risk assessments. The TES Committee did not address the FQPA requirement because of the Agency's pending assessment of organophosphates and their neurotoxic potential (TES Document, 2/27/97).

On December 10, 1997, the HED's Hazard Identification Assessment Review Committee (HIARC) met to reevaluate the Uncertainty Factors and MOEs for dietary as well as non-dietary risk assessments. This reevaluation was necessary to ensure consistency with the other organophosphate chemicals that were recently reviewed by the HIARC to address the enhanced sensitivity of infants and children as required by the FQPA. At the meeting, the Committee evaluated the toxicology database and determined that a reexamination of the subchronic neurotoxicity study in rats, the neuropathology findings from the chronic feeding/carcinogenicity study in rats and the neuropathology data from the one-year dog study should be performed. In addition, a search of the open literature was recommended. These actions were requested to determine whether a developmental neurotoxicity study with azinphos methyl is needed.

On March 19, 1998, the HED's HIARC reconvened to evaluate the results of the reexamination of the subchronic neurotoxicity study in rats, the neuropathology findings from the chronic feeding/carcinogenicity study in rats, the neuropathology data from the one-year dog study, and the search of the open literature on azinphos methyl. The HIARC also addressed the potential sensitivity of infants and children as required by the Food Quality Protection Act (FQPA) of 1996. The application of the FQPA safety factor for the protection of infants and children as required by FQPA, was determined by the HED FQPA Safety Factor Committee.

The conclusions of the March 19, 1998 HIARC meeting, which included a determination of the Uncertainty Factors and/or the Margins of Exposure for the exposure scenarios identified (acute and chronic dietary, as well as, occupational/residential risk assessments), recommendations for aggregate exposure and risk assessments, and the determination of the potential susceptibility to infants and children, are presented in the April 20, 1998 report of the HIARC. The 4/20/98 HIARC report supersedes previous RfD and TES Committee reports. All toxicity endpoints used in this document for the risk characterization are from the 4/20/98 HIARC report.

a. Toxicology Database

The toxicological database on Azinphos-methyl is adequate to support reregistration eligibility. A profile of the toxicological database is given in Table 2.

Table 2. Toxicology Profile

Guideline	Study Type	MRID No.	Required	Satisfied
81-1	Acute oral (rats)	00155002	yes	yes
81-2	Acute dermal (rabbit)	40280102	yes	yes
81-3	Acute inhalation (rats)	40280103	yes	yes
81-4	Primary eye irritation (rabbit)	43337501	yes	yes
81-5	Primary dermal irritation (rabbit)	43337101	yes	yes
81-6	Dermal sensitization (guinea pig)	41064401	yes	yes

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Table 2. Toxicology Profile				
Guideline	**Study Type**	**MRID No.**	**Required**	**Satisfied**
81-8	Acute neurotoxicity (rats)	43360301	yes	yes
82-2	21-day dermal (rabbit)	00145715	yes	yes
82-4	Subchronic inhalation (rats)	00155011	no	yes
82-7	Subchronic oral (rats)	43826601	yes	yes
82-7	Subchronic oral (dogs)	00156424	yes	yes
83-1(b)	Chronic oral - 1 year (dogs)	41804801	yes	yes
83-1(b)	Chronic oral - 2 years (dogs)	41804801	yes	yes
83-1(a) & 83-2(a)	Chronic/carcinogenicity oral - 2 years (rats)	41119901	yes	yes
83-2(b)	Carcinogenicity - 2 years (mice)	00147895	yes	yes
83-3(a)	Developmental- oral teratology (rats)	40464801	yes	yes
83-3(b)	Developmental - oral teratology (rabbit)	40713901 & 41240001	yes	yes
83-4	Reproductive - 2 generation (rats)	40332601	yes	yes
83-4	Reproductive - 1 generation (rats)	41916801	no	supplemental
84-2	Mutagenicity	40280107 40301301 40367811 00155017	yes	yes
85-1	Metabolism	40836501	yes	yes
85-3	Dermal absorption	42452701		yes

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b. Acute Toxicity/Skin Sensitization

Table 3 below summarizes the results, endpoints, and toxicity categories for the acute toxicity studies.

Table 3. Acute Toxicity of Azinphos Methyl

Guideline No.	Study Type	MRID No(s).	Results	Toxicity Category
81-1	Acute Oral(Rat)	00155002	LD_{50} =4.6 mg/kg♂ 4.4 mg/kg♀	I
81-2	Acute Dermal (Rabbit)	40280102	LD_{50} =>2000 mg/kg	III
81-2	Acute Dermal (Rat)	00155003	LD_{50} =200-250 mg/kg♂ 155 mg/kg♀	I
81-3	Acute Inhalation (Rat)	40280103	LC_{50} = >0.21mg/L	II
81-4	Primary Eye Irritation (Rabbit)	43337501	No ocular effects at 48 hrs.	III
81-5	Primary Skin Irritation (Rabbit)	43337101	Non-irritating	IV
81-6	Dermal Sensitization (Guinea Pig)	41064401	Sensitizer	N/A

c. Subchronic Toxicity

i. 21- Day Dermal Toxicity in Rabbits (82-2). Male and female New Zealand White rabbits (6/sex/dose) received repeated dermal applications of azinphos-methyl technical (94.1% ai), at doses of 0, 2, or 20 mg/kg, 6 hours/day, 5 days/week, for a total of 15 applications over a three week period. The Dermal NOAEL was ≥20 mg/kg (highest dose tested; a LOAEL was not determined). The Systemic NOAEL in both sexes was 2 mg/kg/day and the LOAEL was 20 mg/kg/day, based on decreased erythrocyte cholinesterase activity; increased spleen and kidney weights [males]; and decreased body weight gain [females]). At the LOAEL, the following effects were observed: decreased body weight gain (40-70%) in females; decreased (10%) red cell count in males; decreased (24-38%) erythrocyte (red blood cell) cholinesterase activity in both sexes on day 10 and 15 of treatment; increased spleen and kidney weight in males; increased incidence of inflammatory changes in kidneys of males (severity not stated). Measurement of plasma and brain cholinesterase at the 2 and 20 mg/kg/day dose levels showed no effect of treatment in this study.

ii. Subchronic Oral Toxicity in Dogs (82-7). In a 19-week toxicity study in dogs, dietary levels of 0, 20, 50, 100, 200, or 400 ppm were administered to 1 dog/sex/dose. Cholinesterase inhibition (whole blood) was observed at all dose levels and was dose related (35% at 20 ppm to 80% at 400 ppm). These reductions in cholinesterase activity are considered statistically significant. The LOAEL was 20 ppm (lowest dose tested; a NOAEL was not determined). (MRID 00156424).

iii. Subchronic Inhalation in Rats (82-4). The endpoint from this study (MRID 00155011) was selected to be used for short-term and intermediate-term inhalation occupational risk assessments. The NOAEL was determined to be 0.0012 mg/L, and the LOAEL was determined to be 0.0047 mg/L. In a subchronic inhalation toxicity study, male and female Wistar rats were exposed to azinphos-methyl aerosol at concentrations of 0.195, 1.24, or 4.72 mg/m^3 (equivalent to 0.0002, 0.0012, or 0.0047 mg/L, respectively) for 90 days, 6 hr/day, 5 days/week. Plasma and red blood cell cholinesterase inhibition (30-40%) were observed in males and females at 0.0047 mg/L.

d. Chronic Toxicity and Carcinogenicity

i. Oral Toxicity Study in Dogs - One Year (83-1(b)). The endpoint from this study (MRID 41804801) was selected to be used to determine the chronic RfD and for chronic occupational risk assessments. The NOAEL was 0.149 mg/kg/day for males and 0.157 mg/kg/day for females, and the LOAEL was 0.688 mg/kg/day for males and 0.775 mg/kg/day for females, based on the above noted significant decreases in erythrocyte cholinesterase activity in both sexes as well as increased incidence of diarrhea in males. In a 52-week toxicity study, azinphos-methyl technical (91.9%) was administered to male and female beagle dogs (4/sex/group) at dose levels of 0, 5, 25, or 125 ppm (0.149, 0.688, or 3.844 mg/kg for males; 0.157, 0.775, or 4.333 mg/kg for females). Both sexes of dogs at 125 ppm dose level exhibited decreases in plasma cholinesterase (52-58%) erythrocyte cholinesterase (66-92%), and brain cholinesterase (20-27%) beginning at week 4 of treatment and continuing until week 52. At the 125 ppm dose level, cytochrome P-450 N- and O-demethylase activity was increased 39% in male dogs. Serum albumin and A/G (adenine to guanine) ratio was reduced by 13% and 20% respectively in male dogs after 13 weeks of exposure. Mucoid diarrhea and occasional emesis were also observed at this dose level in male and female dogs. At the 25 ppm dose level, erythrocyte cholinesterase activity was decreased by 27-40% below control in male dogs, and by 35-43% in female dogs. Increased incidence of mucoid diarrhea was also observed.

ii. Oral Toxicity in Dogs - Two Years (83-1(b)). Based on the time weighted average, the NOAEL was 5 ppm (0.125 mg/kg/day) and the LOAEL was 39.2 ppm (0.98 mg/kg/day), based on inhibition of erythrocyte cholinesterase (MRID 41804801). In a two-year toxicity study in dogs, four groups of male and female Cocker Spaniel dogs (4/sex/dose) received azinphos-methyl technical (purity not stated) in the diet at 0, 5, 20, or 50 ppm. After 36 weeks on test diets, the 20 ppm and 50 ppm dose groups were given 50 ppm and 100 ppm respectively,

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based on the lack of toxic symptoms in these dose groups. After 57 weeks on test diets, the 100 ppm dose group was increased to 150 ppm and again to 300 ppm after 84 weeks on test diets. Plasma and erythrocyte cholinesterase activity were measured weekly 5 weeks prior to treatment and then weekly starting at 4 weeks after start of treatment. After the dose was increased to 300 ppm, clinical signs of toxicity (fine muscle tremors of the hind limb, lethargy, weakness) were observed, as were decreased food consumption and body weight. Inhibition of plasma cholinesterase activity ranged 25 to 50% over the 50 to 300 ppm dosing range. Inhibition of erythrocyte cholinesterase ranged from 35 to 80% over the 20 to 100 ppm dosing range. Cholinesterase inhibition generally increased with increasing dose. These reductions in cholinesterase activity are considered significant.

iii. Oral Toxicity in Rats - Two Years (83-1(a)/83-2(a)). There was no evidence of carcinogenicity from treatment with azinphos-methyl in this study. (MRID 41119901). However, for chronic toxicity, the NOAEL was 0.25 mg/kg/day in males and 0.31 mg/kg/day in females, and the LOAEL was 0.75 mg/kg/day in males and 0.96 mg/kg/day in females, based on decreases in plasma cholinesterase (females), erythrocyte cholinesterase (both sexes), and brain cholinesterase (females). In a combined chronic toxicity and carcinogenicity study in Wistar rats, technical azinphos-methyl (87.2% ai) was administered in the diet at dose levels of 0, 5, 15, or 45 ppm (0.25, 0.75, or 2.33 mg/kg/day in males; 0.31, 0.96, or 3.11 mg/kg/day in females) for 104 weeks. There were no treatment-related effects on mortality, hematology, clinical chemistry, gross pathology, or histopathology. Over the period of treatment at 45 ppm, plasma cholinesterase was decreased by 38-49% in males and 54-67% in females and erythrocyte cholinesterase was decreased by 20-37% in males and by 23-31% in females. Also at this dose, at 12 months, brain cholinesterase was decreased 50% in female rats, and was also decreased 32-55% in males and females at study termination. Relative weight of the liver in females was increased 9% at the 45 ppm dose level. At 15 ppm, plasma cholinesterase was decreased by 19-35% in females, erythrocyte cholinesterase was decreased by 10-22% in males and 12-20% in females, and brain cholinesterase by 21% in females over the 24 month test period. At 5 ppm, erythrocyte cholinesterase was decreased by 12% in male rats at study termination. A 20% decrease in cholinesterase activity is considered significant. The high dose of 45 ppm was determined to be adequate for carcinogenicity testing based on the clear evidence of compound toxicity (i.e., inhibition of cholinesterase).

iv. Oral Toxicity in Mice - Two Years (83-2(b)). There was no evidence of carcinogenicity from treatment with azinphos-methyl in this study (MRID 00147895). A two-year carcinogenicity study was conducted in male and female CD-1 mice in which 50 mice/sex/dose were administered technical azinphos methyl (88.6%) in the diet at dose levels of 0, 5, 20, or 80/40 ppm (0.79, 3.49, or 11.33 mg/kg/day in males; 0.98, 4.12, or 14.30 mg/kg/day in females) for 104 weeks. The NOAEL was less than (<) 0.79 mg/kg/day in males and <0.98 mg/kg/day in females and the LOAEL was 0.79 mg/kg/day in males and 0.98 mg/kg/day in females, based on decreased erythrocyte cholinesterase activity in males and females. There were no significant treatment-related effects on body weight, body weight gain, food consumption, hematology, organ weights, macroscopic pathology, or microscopic pathology at the 40 pm dose level and below. However, at the 40 ppm dose level, plasma cholinesterase in males was decreased 34-52% and in females was decreased 23-33% vs the control. Erythrocyte cholinesterase was decreased 19-50% in males and 23-54% in females. Brain cholinesterase (measured only at 24 months) was decreased to 37% of control in males and to 33% of control in females. At the 20 ppm dose level, plasma cholinesterase in males was decreased 69-83% of control and decreased 50-77% of control in females. Erythrocyte cholinesterase was decreased 43-66% of control in males and 45-51% of control in females. Brain cholinesterase was decreased to 84% of control in males and 74% of control in females. At the 5 ppm dose level, erythrocyte cholinesterase was decreased 84-95% of control in males and 78-93% of control in females. Plasma cholinesterase was largely unaffected except in females at 12 months, where inhibition at 84% of the control was observed.

e. Developmental Toxicity

i. Oral Teratology Study in Rats (83-3(a)). For maternal toxicity, the NOAEL was 0.5 mg/kg/day and the LOAEL was 1.0 mg/kg/day, based on decreased maternal brain cholinesterase activity. For developmental toxicity, the NOAEL was 2.0 mg/kg/day, the highest dose tested; a LOAEL was not established (MRID 40464801). In a developmental toxicity (teratology) study, rats of the Crl:CDBR strain from Charles River received either 0, 0.5, 1.0, or 2.0 mg/kg/day azinphos-methyl technical (87.7% ai) by oral gavage on gestation days 6 through 15 inclusive (33 dams/dose). There were no reported treatment effects on maternal mortality, body weight, food consumption, or cesarean section observations at any dose level tested. No malformations of either the viscera or skeleton were reported for the fetuses of any group at any dose level tested. At the 1.0 mg/kg/day dose level, maternal brain cholinesterase activity was significantly reduced by 8% compared to control, but no corresponding decrease in fetal brain cholinesterase was observed.

ii. Oral Teratology Study in Rabbits (83-3(b)). For maternal toxicity, the NOAEL was 1.0 mg/kg/day and the LOAEL was 2.5 mg/kg/day, based on decreased plasma and erythrocyte cholinesterase activity. For developmental toxicity, the NOAEL was 2.5 mg/kg/day and the LOAEL was 6.0 mg/kg/day, based on the increased pre- and post-implantation loss observed at this dose. (MRID 40713901 and 41240001). A developmental toxicity study was conducted in American Dutch rabbits, which received either 0, 1.0, 2.5, or 6 mg/kg/day azinphos methyl technical (87.7%) by oral gavage on gestation days 6 through 18 inclusive. At the 6.0 mg/kg/day dose level, two to four maternal rabbits exhibited tremors and/or ataxia during the study. There were no compound related effects on body weight, food consumption, or gross pathology in maternal rabbits at any dose level tested. On gestation day 19, activity of plasma and erythrocyte cholinesterase was decreased by 13% and 20.5% respectively at the 2.5 mg/kg/day dose level, and by 22.4 and 50.1% at the 6.0 mg/kg/day dose level, respectively. A statistically significant increase in pre-implantation loss and a numerical increase in post-implantation loss was observed at the 6.0 mg/kg/day dose level, with a significant decrease in live fetuses/does at the 6.0 mg/kg/day dose level.

f. Reproductive Toxicity

i. 2-Generation Reproductive Toxicity Study in Rats (83-4). In a two-generation reproduction study in Wistar rats (MRID 40332601; Doc No. 06533), azinphos methyl (87.2%) was administered at dietary concentrations of 0, 5, 15, or 45 ppm (equivalent to 0.25, 0.75, or 2.25 mg/kg/day). The systemic parental NOAEL was 15 ppm (0.75 mg/kg/day), based upon mortality of dams, decreased body weight for P males and F1 males and females, and clinical signs of toxicity, including poor condition and convulsions, at the systemic LOAEL of 45 ppm (2.25 mg/kg/day). The reproductive (offspring) NOAEL and LOAEL were 5 and 15 ppm (0.25 and 0.75 mg/kg/day), respectively. The LOAEL was based on a reduction in pup viability and lactation indices (death of the offspring between the time periods of postnatal days 0-5 and 5-28) and decreased mean total litter weights at weaning on postnatal Day 28. No cholinesterase measurements were taken for either parental animals or pups.

ii. 1-Generation Reproductive Study in Rats (83-4). In a supplementary one-generation toxicity study in Wistar rats (MRID 41916801), 92% azinphos methyl was administered at dietary concentrations of 0, 5, 15, or 45 ppm (equivalent to 0.43, 1.30, or 3.73 mg/kg/day for males and 0.55, 1.54, or 4.87 mg/kg/day for females). The maternal systemic NOAEL was <5 ppm (0.55 mg/kg/day), based upon plasma and erythrocyte cholinesterase inhibition on day 5 of lactation at 5 ppm, the lowest dose tested. Further characterization of maternal cholinesterase inhibition revealed that plasma, RBC, and brain ChE were significantly decreased in females at 45 ppm at all time points tested (end of premating, gestation Day 11, lactation Day 5 and lactation Day 28). At 15 ppm, plasma and RBC (not brain) ChE were significantly inhibited at the same time points. For males at the end of mating, plasma ChE was significantly decreased at 15 and 45 ppm, while RBC ChE was significantly decreased at 5, 15, and 45 ppm; brain ChE was not decreased at any dietary level. The reproductive (offspring) NOAEL and LOAEL were 5 and 15 ppm (0.55 and 1.54 mg/kg/day), respectively. The LOAEL was based on a reduction in the pup viability index (death of the offspring during postnatal days 0-5) and decreased pup weights at postnatal Days 14 and 21. Pup brain weight and cholinesterase activity were assessed in pups at postnatal Days 5 and 28. At 45 ppm, significant reductions in brain cholinesterase activity was noted in pups at each interval (Days 5 and 28), and a significant reduction in brain weight was observed on postnatal Day 5, but not Day 28.

g. Mutagenicity (84-2)

In an Ames Salmonella assay, azinphos-methyl technical (100% ai)was tested for the ability to cause gene mutations in *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA98, and TA100 in the absence and presence of metabolic activation (Aroclor 1254 induced rat liver S-9). Azinphos-methyl technical at concentrations of 0, 2, 10, 40, 80, or 160 μg/plate in the absence and presence of metabolic activation showed no evidence of mutagenicity in this study (MRID 40280107).

In another Ames Salmonella assay, azinphos-methyl (88.8% ai) was tested for mutagenic activity in *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA100, and TA98 with and without metabolic activation at concentrations of 0, 33, 100, 333, 1000, 2000, 3333, or 4000 μg/plate. There was no evidence for mutagenicity at any concentration tested in the absence or presence of metabolic activation (MRID 40301301).

In an *in vitro* cytogenetics assay using human lymphocytes, azinphos-methyl (91.9% ai) was tested under non-activated conditions at concentrations of 0, 1, 10, or 100 μg/ml and under S-9 activated conditions at concentrations of 0, 5, 50, or 500 μg/ml. Under non-activated conditions, azinphos-methyl was found to be non-clastogenic at all concentrations tested. Under activated conditions, azinphos-methyl was found to be clastogenic at 500 μg/ml (MRID 40367811).

The registrant submitted a primary rat hepatocyte unscheduled DNA synthesis assay (MRID 00155017). In that study, azinphos methyl (91.1%) was found to be negative up to the highest dose tested (50.3 μg/ml).

h. Metabolism (85-1)

The metabolism of [^{14}C]azinphos-methyl was examined in male and female Sprague-Dawley rats following oral administration of single doses of 0.125 or 2.5 mg/kg, or after a repeated oral dose of unlabeled test material at 0.125 mg/kg for 14 days followed by a single radiolabelled dose. Within 72 hours post-dose, between 92-109% of the administered radioactivity was excreted across all dose groups. Between 63-79% of the administered radioactivity was eliminated in urine, and between 20-27% in feces. Highest residual concentrations of radioactivity were observed in blood (0.013-00.319 μg/g tissue), kidney (0.008-0.257 μg/g tissue), liver (0.005-0.121 μg/g tissue), lung (0.008-0.172 μg/g tissue), and brain (0.004-0.126 μg/g tissue). Approximately 75% of the administered radioactivity was identified. The cysteinyl methyl benzazimide sulfone (13-20% of the dose) and the methyl-sulfonylmethylbenzazimide (14-20% of the dose) were identified as the major urinary metabolites. In feces, the methylsulfonylmethylbenzazimide, cyteinylmethylbenzazimide sulfoxide, desmethyl isoazinphos-methyl, azinphos-methyl oxygen analog, and methylthiomethylbenzazimide were identified, but did not comprise greater than 5% of the administered dose. No azinphos-methyl or glucuronic or sulfate conjugates were found in urine or feces. In vitro studies of azinphos-methyl metabolism supported the in vivo studies suggesting that metabolism of azinphos-methyl in rats proceeds largely through the actions of glutathione-S-transferase and mixed function oxidase. There were no major sex- or dose-related differences in disposition and metabolism of azinphos-methyl in this study (MRID 40836501).

i. Dermal Absorption (85-3)

A 35% wettable powder formulation of azinphos-methyl was applied dermally to rats at 0.93, 9.3, and 93 $\mu g/cm^2$ exposure, equivalent to 0.056, 0.56, or 5.6 mg (ai)/kg. Duration of exposure for six groups of four male rats/dose was 1, 4, 10, 24, 72, or 168 hours. By 10 hours, 32.2, 22.1, and 23.7% of the applied doses of 0.056, 0.56, and 5.6 mg/kg, respectively, remained on the skin. To simulate worker exposure, the test site of animals exposed for 24, 72, and 168 hours was wiped with a moistened gauze pad after 10 hours of exposure. Maximum systemic absorption occurred from the 168 hour exposure with 41.7, 21.9, and 18.3% of the applied dose recovered in blood, urine, feces, carcass, and cage wash combined for the 0.056, 0.56, and 5.6 mg/kg doses, respectively. From these data, the value of 41.7% absorption was used as a measure of dermal absorption for azinphos-methyl. In the high-dose group, red blood cell cholinesterase inhibition at 10 - 24 hours was significantly lower (by 16-17%) than control. No effects on plasma cholinesterase inhibition were noted at any dose level and no effects on red blood cell cholinesterase were seen at levels $\leq$0.56 mg/kg. Based on red blood cell cholinesterase inhibition, the NOAEL and LOAEL are 0.56 mg/kg and 5.6 mg/kg, respectively. (MRID 42452701).

j. Neurotoxicity

i. Acute Delayed Neurotoxicity in Hens (81-7). In an acute delayed neurotoxicity study in hens (MRID 40883101; Doc. No. 007132), 85% azinphos methyl was administered at 330 mg/kg in corn oil. A second dose was given by gavage at study day 21. Mortality was extensive (18/30 hens died within 3-4 days of the initial dose and one additional hen died following the second dose), and clinical signs of neurotoxicity were observed (grade 5 ataxia, prostration, hypoactivity, liquid feces). No gross or microscopic evidence of neuropathology (nonperfused tissues) was observed. Neurotoxic esterase (NTE) was not apparently measured. The RfD/Peer Review Committee confirmed the opinion that neuropathological observations of degeneration digestion chamber of sciatic nerves and perivascular cuffing of the brain in the treated animals were not treatment-related.

ii. Acute Neurotoxicity Study in Rats (81-8). The endpoint from this study (MRID 43360301) was selected to be used for determining the acute RfD for the acute dietary risk assessment. The NOAEL for neurotoxicity was not determined; the LOAEL was determined to be 1 mg/kg/day. In an acute neurotoxicity study in Fischer 344 rats (18/sex/group), 92.2% azinphos methyl was administered in 0.5% methylcellulose and 0.4% Tween 80 in deionized water by a single gavage dose of 2, 6, or 12 mg/kg for males and 1, 3, or 6 mg/kg/ for females, in a volume of 5 ml/kg. Cholinesterase inhibition in all three biomarkers (plasma, erythrocyte, and brain) was observed at the lowest dose tested (2 mg/kg for males and 1 mg/kg for females)and attributed to treatment; brain cholinesterase inhibition and increased incidences of neurobehavioral effects were observed in males and females at 6 and 3 mg/kg and above. The neurobehavioral signs included gait incoordination, repetitive chewing, muscle fasciculations, tremors, hypoactivity, no reaction to touch, abnormal righting reflex, decreased body temperature, decreased forelimb and/or hind limb grip strength, and decreased motor and locomotor activities. A high incidence of mortality (5/18 males and 15/18 females) was observed at 12/6 mg/kg (M/F). Brain weights and neuropathology findings were reported to be similar between control and treated animals.

iii. Subchronic Neurotoxicity in Rats (82-5). As part of a response to a Data Call-In Notice of June 16, 1993, the registrant submitted a subchronic neurotoxicity study conducted with the technical grade (92.2%) of azinphos methyl in male and female Fischer 344 rats. In this study (MRID 43826601), groups of 18 male and 18 female rats were administered the technical grade of azinphos-methyl in the diet for 13 weeks at nominal doses of 0, 15, 45, or 120 ppm for males (0, 0.91, 2.81, and 7.87 mg/kg/day mean intake) and 0, 15, 45, or 90 ppm for females (0, 1.05, 3.23, and 6.99 mg/kg/day mean intake). Twelve rats per sex per dose were used for neurobehavioral evaluation, with half used for neuropathology. The remaining six per sex per dose were used for cholinesterase determination. A statistically significant (>20%) inhibition of red cell cholinesterase was observed at all dose levels tested in this study, as was a statistically significant inhibition (>20%) of plasma and brain cholinesterase at the mid and high dose. Decreased forelimb grip strength, motor activity, and locomotor activity were observed in both sexes at the high dose, but did not correlate definitively with any pathology of the nervous system. Based on the data in this study, the systemic LOAEL = 15 ppm (~ 1.0 mg/kg/day) for male and female rats, based on a statistically significant (>20%) inhibition of red cell cholinesterase. The systemic NOAEL was < 5 ppm and estimated to be 5 ppm (0.3 mg/kg/day) for male and female rats, based on extrapolation of cholinesterase inhibition data. Although significant signs of cholinergic toxicity were observed in this study, there was no definitive evidence of a neurotoxic effect for azinphos-methyl in this study (MRID 43826601).

The neuropathology findings were equivocal, but suggested treatment-related effects in the brain (axonal swelling of minimum severity in males) and spinal cord (nerve fiber degeneration of the cauda quina and the cervical and/or thoracic cord in both sexes) at the high dose (120 ppm; 7.87/6.99 mg/kg/day in M/F). In females, the DER noted a possible correlation between the incidence of cervical spinal cord lesions at the high dose and decreased forelimb grip strength at all dose levels. Since the histopathology tables were not included in the DER, the RfD/Peer Review Committee recommended that the incidence and severity of the equivocal neuropathological findings be reassessed. Based on a most recent reevaluation of the neuropathology data by the Hazard Identification Assessment Review Committee (HIARC) (see Memo dated March 19, 1998), it was concluded that neither the incidence nor the severity of the neuropathological lesions noted in high-dose males and females could be attributed to treatment with azinphos methyl. The findings were not statistically significant, of minimal severity, and occurred sporadically.

iv. Developmental Neurotoxicity. At the RfD Peer Review Committee meeting on September 16, 1993, it was recommended that a developmental neurotoxicity study in rats be conducted with azinphos methyl because it is a potent cholinesterase inhibitor. In retrospect, the following additional information was considered by the HIARC:

- Evidence that support requiring a developmental neurotoxicity study:

  - Structural Activity Relationship (SAR) concern: Azinphos methyl is an organophosphate.

  - Administration to various species (rat, mouse, dog) results in cholinesterase inhibition in the plasma, erythrocytes and/or brain. Systemic evidence of cholinergic effects occurs regularly in the data. Guideline neurotoxicity studies have been submitted and demonstrate neurobehavioral effects.

  - In a one-generation reproduction study in rats, dietary administration of azinphos methyl (HDT) to parental animals resulted in a significant decrease in pup brain weight on postnatal Day 5 but not Day 28, but was subsequently found to be insignificant.

- Evidence that do not support requiring a developmental neurotoxicity study:

  - With the exception cited above of decreased pup brain weight in the one-generation reproduction study, no effects on brain weight or histopathology of the brain or peripheral system (without perfusion) were observed in any of the guideline subchronic or chronic studies in which these parameters were measured.

  - No evidence of abnormalities in the development of the fetal nervous system were observed in the prenatal developmental toxicity studies in either rats or rabbits at maternally toxic oral doses up to 2.0 or 6.0 mg/kg/day, respectively.

  - A search of the open literature from 1969 to the present revealed no evidence of neuropathology in treated animals. No studies were found in the open literature regarding potential adverse effects associated with humans accidentally or occupationally exposed to azinphos methyl.

  - Azinphos methyl did not cause delayed neurotoxicity in hens following acute exposure.

Based on the weight-of-the-evidence, the HIARC determined that a developmental neurotoxicity study is not required.

v. General Neurotoxicity Observations. In addition to the clinical signs of neurotoxicity which were observed in the neurotoxicity studies in rats, the following additional clinical observations that are indicative of neurotoxicity were seen: occasional emesis and mucoid diarrhea at 125 ppm (0.688 mg/kg/day) in the 1-year dog study, convulsions at 2.25 mg/kg/day in the two-generation reproduction study in rats, and tremors at 6 mg/kg/day in the prenatal developmental toxicity study in rabbits. Similarly, ChE inhibition (plasma, RBC, and brain) was observed at low dose levels in all subchronic and chronic studies in which this parameter was measured.

In contrast, there was no indication of decreased brain weight or histopathology of the brain or peripheral nervous system, following processing of tissues without perfusion, in any of the guideline subchronic or chronic studies. The Committee, however, noted that numerous neurological tissues were apparently not assessed in the chronic dog study (MRID 41804801) and that histopathology tables were not provided in the DER of the chronic rat study (MRID 41119901).

However, a reexamination of the neuropathology data presented in the one-year dog study (see Memo dated March 19, 1998) indicated that no lesions were found in the brain, spinal cord, eyes, optic nerve or sciatic nerve. Samples of the above tissues were processed and examined microscopically for all animals in all study groups.

Similarly, a reevaluation of the neuropathology data from the chronic rat study (see Memo dated March 9, 1998) revealed that neither the peripheral nerve nor the spinal cord were examined histologically. Although this study is currently classified as Acceptable, it does not fully satisfy the guideline requirements for a chronic feeding/carcinogenicity study (83-1) in rats. However, it was not chosen as a critical study for the toxicity endpoint selection. In addition, reassessment of the brain weight data in this study, indicated that significantly increased relative brain weights in males of the mid-(15 ppm) and high-(45 ppm) dose groups at 12 months and in high-dose males at 24 months were accompanied by significant body weight reductions. However, absolute brain weights for these groups showed nonsignificant less than or equal to 3% increases. It was concluded, therefore, that the apparent increase in relative brain weights was an artifact resulting from decreased body weight.

The reevaluation of the data related to neurological findings indicates that while azinphos methyl is a potent cholinesterase inhibitor, there is no evidence in the submitted studies or the open literature that demonstrate an association between exposure to the test chemical and histopathological effects on the nervous system of either the rat or the dog.

k. Hazard Characterization

Azinphos methyl is an organophosphate pesticide. The toxicology database provides clear, solid evidence confirming that azinphos methyl has anticholinesterase activity in various species including dogs, rabbits, rats, mice and hens. In acute toxicity studies, azinphos methyl exhibits low to high toxicity depending on the route of administration and the species used. It is acutely toxic at relatively low oral or dermal doses when tested in rats but found to have low toxicity in rabbits exposed dermally. This finding supports the earlier arguments regarding the suitability of conducting rabbit dermal studies on organophosphates (see Short-Term Dermal Risk Assessment).

The data from the only available acute inhalation study suggest that azinphos methyl is moderately toxic via this route. It is only slightly irritating to the eye and non-irritating to the skin but did produce dermal sensitization in guinea pigs. Other toxic signs observed in animals treated acutely with azinphos methyl are consistent with cholinesterase inhibition and are typical of the acute toxic signs induced by the organophosphate class of chemicals. They included: tremors, convulsions salivation, and dyspnea (labored breathing). Dose-related inhibition of plasma, erythrocyte and brain cholinesterase (ChE) activity occurs by all routes of exposure and following exposure for various durations.

Although frank neurobehavioral observations have been noted in acute and subchronic studies, there is no evidence of histopathological effects on the central nervous system. Similarly, azinphos methyl did not cause delayed neurotoxicity in hens and there was no evidence of neuropathology in chronic studies.

There is also no indication of an increased susceptibility of the fetuses or offspring of rats or rabbits after pre-natal and/or postnatal exposure to azinphos methyl. In all studies examined, maternal or parental NOAELs are lower or equivalent to the developmental offspring NOAELs. Based on these considerations, the weight-of-the-evidence evaluation of the database does not indicate the need for evaluation of functional development and, thus, there does not appear to be a need to conduct a developmental neurotoxicity study.

Azinphos methyl has been classified in "Group E" (i.e., "Not Likely" to be carcinogenic in humans via relevant routes of exposure) because there is no evidence that azinphos methyl altered the spontaneous tumor profile in rats or mice. In both studies, the highest dose tested was considered adequate for carcinogenicity testing based on cholinesterase inhibition. Similarly, there is no mutagenicity concern.

Based on metabolism studies in rats, azinphos methyl is degraded and/or eliminated within 72 hours post-dosing and does not accumulate in tissues. The metabolism of azinphos methyl in rats proceeds largely through the action of glutathione-S-transferase and mixed function oxidases. There were no major sex- or dose-related differences in the disposition or metabolism of azinphos methyl.

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2. Dose Response Assessment

a. FQPA Issues: Uncertainty/Safety Factor/Special Sensitivity

Under the Food Quality Protection Act (FQPA), the Agency was directed to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

Pursuant to the language and intent of the FQPA directive regarding infants and children, the applicable toxicity database for azinphos methyl was evaluated by the Hazard Identification Assessment Review Committee (HIARC). The final recommendation on the FQPA Safety Factor, however, was made by the FQPA Safety Factor Committee (the Committee) based on recommendations from the HIARC. The Committee determined that the 10X safety factor should be removed for azinphos methyl. The Committee considered the following information in their decision.

i. Adequacy of Data. The data included an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits, meeting the basic data requirements, as defined for a food-use chemical by 40 CFR Part 158. At the Hazard Identification Assessment Review Committee (HIARC) meeting on azinphos methyl (March 19, 1998) it was determined that a developmental neurotoxicity study was not required.

ii. Susceptibility Issues. The developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity of young rats or rabbits following *in utero* exposure to azinphos methyl. In the prenatal developmental toxicity study in rats, no evidence of developmental toxicity was seen even in the presence of maternal toxicity (cholinesterase inhibition).

In the two-generation reproduction study in rats, however, there was a suggestion of increased sensitivity to the offspring following pre-and/or postnatal exposure to azinphos methyl. In both the one- and two-generation studies, decreased pup survival in both early and late stages of lactation and pup weight reductions in late lactation were observed. In the two-generation study, these effects in the offspring were observed at a dietary level which was not systemically toxic to the parental animals. It was noted, however, that parental toxicity in the one-generation study was based upon decreased cholinesterase activity, while cholinesterase measurements were not

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conducted in the two-generation study, and the parental toxicity was based upon mortality, clinical signs, and body weight decrements (less sensitive indicators). The HIARC, therefore, concluded that the suggested susceptibility of the offspring was an artifact of the study design.

Comparative cholinesterase inhibition data for adult rats and their fetuses or pups did not identify increased susceptibility to the offspring. In the prenatal developmental toxicity study in rats, brain cholinesterase activity did not appear to be significantly inhibited in GD20 rat fetuses following *in utero* exposure, even at a dose which demonstrated marked brain cholinesterase inhibition in the dams on the same day of gestation. Brain cholinesterase inhibition in 5- and 28-day old pups of the one-generation reproduction study occurred at the highest dietary level tested; however, brain cholinesterase inhibition was also observed in maternal animals at this dose level at termination.

The FQPA Safety Factor Committee determined that the additional FQPA Safety Factor should be removed because:

- Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposure in rats and rabbits.

- Both a one- and a two-generation reproductive toxicity study in rats showed no increased susceptibility in pups when compared to adults.

- There was no evidence of abnormalities in the development of the fetal nervous system in the pre/postnatal studies. Neither brain weight nor histopathology (nonperfused) of the nervous system was affected in the subchronic and chronic toxicity studies.

- The toxicology database is complete based on current requirements and there are no data gaps. There is no evidence to require a developmental neurotoxicity study.

b. Reference Dose (RfD) for Chronic Oral Exposure

On September 16, 1993, the Health Effects Division RfD/Peer Review Committee evaluated the toxicology database for azinphos methyl to establish a Reference Dose (RfD). An RfD of 0.00149 mg/kg/day was derived, based on the NOAEL of 0.149 mg/kg/day established in male dogs in a 1-year chronic toxicity study (MRID 41804801) and using an uncertainty factor of 100 (10 for inter- and 10 for intra-species variations). The LOAEL in this study, 0.69 mg/kg/day, was based on decreases in erythrocyte cholinesterase. The World Health Organization in 1991 established an Acceptable Daily Intake (ADI) of 0.005 mg/kg/day for azinphos-methyl.

c. Carcinogenicity Classification

At the September 1993, meeting of the RfD/Peer Review Committee, azinphos methyl was classified as a "not likely" human carcinogen. This classification was based on the lack of evidence of carcinogenicity in male and female CD-1 mice (MRID 00147895) and in male and female Wistar rats (MRID 41119901). In both studies, the highest dose tested was considered adequate for carcinogenicity testing based on cholinesterase inhibition. Treatment with azinphos methyl did not alter the tumor profile in the above strain of mice or rats. The HIARC concurred with these conclusions and re-affirmed the previous classification.

d. Summary of Toxicological Endpoints for Use in Human Risk Assessment

The Health Effects Division Hazard Identification Assessment Review Committee (HIARC) considered the available toxicology data for azinphos-methyl at a meeting held on March 19, 1998. Toxicology endpoints and dose levels of concern were identified for use in risk assessment corresponding to acute dietary exposure, short and intermediate term occupational and residential exposure, and chronic occupational and residential exposure. Percentage of dermal absorption was also determined.

i. Acute Dietary. To estimate acute (one-day) dietary risk, the endpoint selected was cholinesterase inhibition. An acute RfD of 0.003 mg/kg/day based on a LOAEL of 1 mg/kg from an acute neurotoxicity study in rats (MRID 43360301) was identified for use in acute dietary risk assessments. This LOAEL was selected based on inhibition of plasma, erythrocyte, and brain cholinesterase observed following a single dose. Because no NOAEL was established for this study, an additional uncertainty factor of 3 to account for the lack of a NOAEL in the critical study was applied to the existing uncertainty factor for inter-species extrapolation (10X) and intra-species variability (10X) resulting in a total uncertainty factor of 300 for the acute dietary risk assessment.

ii. Chronic Dietary. The chronic RfD of 0.00149 mg/kg/day, based on the NOAEL of 0.149 mg/kg/day established in male dogs in a 1-year chronic toxicity study (MRID 81804801) and using an uncertainty factor of 100, will be used for chronic dietary risk assessments.

iii. Dermal Absorption. Based on a dermal absorption study in rats (discussed above), a value of 41.7% absorption was selected for use in risk calculations (MRID 42452701).

iv. Short and Intermediate Term Occupational and Residential. For short (1 to 7 days) term dermal exposure, the HIARC recommended use of the dermal absorption study in rats (MRID 42452701), which included a determination of ChE inhibition, as appropriate for the Short-Term Occupational Exposure Risk Assessment. Previously, the 21-day dermal toxicity study in rabbits (MRID 00145715) was selected for the Short- and Intermediate-Term Occupational Exposure Risk Assessments. However, during the evaluation

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of the database for azinphos methyl, the HIARC determined that the 21-day dermal toxicity study in rabbits was not appropriate (i.e., the rat toxicity data may be more protective than the rabbit data).

For intermediate (7 days to several months) term exposure, the HIARC selected the one year toxicity study in dogs for this Exposure Risk Assessment. Since an oral NOAEL was selected a dermal absorption factor of 41.7% should be used for this risk assessment. Application of the dermal absorption factor (0.42) to the above NOAEL yields an equivalent dermal dose of 0.36 mg/kg/day. Previously, the 21-day dermal toxicity study in rabbits (MRID 00145715) was selected for the Short- and Intermediate-Term Occupational Exposure Risk Assessments. However, during the evaluation of the database for azinphos methyl, the HIARC determined that the 21-day dermal toxicity study in rabbits was not appropriate (i.e., the rat toxicity data may be more protective than the rabbit data).

For inhalation exposure (any time period), a 90-day inhalation toxicity study (MRID 00155011) was selected with a NOAEL of 0.0012 mg/L. The endpoint was inhibition of plasma and erythrocyte cholinesterase, which was observed at the next highest dose of 0.0047 mg/l in both male and female rats.

v. Chronic Occupational and Residential (non-cancer). Long-term dermal exposure via the dermal route is not expected based on the use pattern. A summary of toxicological endpoints is given in Table 4 below.

Table 4. Summary of Toxicological Endpoints for Azinphos Methyl Risk Assessments

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary	LOAEL = 1.0 UF = 300	Plasma, erythrocyte and brain cholinesterase inhibition	Acute Neurotoxicity-Rat
	Acute RfD = 0.003 mg/kg		
Chronic Dietary	NOAEL= 0.149 UF = 100	Erythrocyte cholinesterase inhibition.	1-Year Toxicity-Dog
	Chronic RfD = 0.00149 mg/kg/day		
Short-Term (Dermal)	Dermal NOAEL = 0.56 MOE = 100	Erythrocyte cholinesterase inhibition.	Dermal Absorption Rat

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Table 4. Summary of Toxicological Endpoints for Azinphos Methyl Risk Assessments			
Exposure Scenario	**Dose (mg/kg/day)**	**Endpoint**	**Study**
Intermediate-Term (Dermal)[1]	Oral NOAEL = 0.149	Erythrocyte cholinesterase inhibition.	1-Year Toxicity-Dog
	MOE = 100		
Long-Term (Dermal)	Not Applicable	Not Applicable	Not Applicable
Inhalation (Any Time Period)	NOAEL= 0.0012 mg/L	Plasma and erythrocyte cholinesterase inhibition.	90-Day Inhalation Rat
	MOE = 100		
[1] A 41.7% dermal absorption factor should be used for the intermediate-term risk assessment.			

3. <u>Dietary Exposure and Risk Assessment/Characterization</u>

a. Dietary Exposure (Food Sources)

The submitted residue chemistry data are adequate to support reregistration. The residue chemistry database is substantially complete; however, magnitude of the residue data are required for walnuts and cotton gin byproducts.

i. OPPTS GLN 860.1200: Directions for Use. A search of the Agency's Reference Files System (REFS) on 12/10/96 indicates that there are nine azinphos methyl end-use products (EPs) with food/feed uses registered to Bayer Corp. These EPs are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
3125-102[1]	7/94	2 lb/gal EC	Guthion® 2L
3125-123[2]	8/94	2 lb/gal EC	Guthion® 2S
3125-193[3]	7/94	50% WP	Guthion® 50% Wettable Powder Crop Insecticide
3125-301[4]	4/96	50% WP	Guthion Solupak® 50% Wettable Powder Insecticide
3125-338	7/94	3 lb/gal FlC	Guthion 3® Flowable Insecticide

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EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
3125-378	7/94	35% WP	Guthion® 35% Wettable Powder Insecticide
3125-379	8/94	35% WP	Guthion Solupak® 35% Wettable Powder Insecticide
3125-426	4/93	2 lb/gal EC	Guthion® 2L
3125-427	4/93	3 lb/gal FlC	Guthion 3® Flowable Insecticide

[1]Includes SLN Nos. MS840012, TX840005.
[2]Includes SLN Nos. CA900021, MA780002, OH810018.
[3]Includes SLN Nos. CA790139, NJ940002, OH810017, VT800004.
[4]Includes SLN Nos. CA790139, CA790149, CA800146, CA810074, CA900012, NJ940003.

Bayer has voluntarily requested cancellation of all the products listed above except for EPA Reg. Nos. 3125-102 and 3125-301 (letter dated 11/5/98 from J.S. Thornton to G. Tompkins).

Labels bearing uses on grapes should be revised to clarify specific use rates that correspond to the PHIs listed. The labels bearing use directions for filberts and pecans should specify a 45-day PHI; the reference to shuck-split for pecans should be deleted from the labels. The FlC labels should be revised to specify a maximum seasonal rate for cotton. (See Table A - Food/Feed Use Patterns Subject to Reregistration).

A comprehensive summary of the registered food/feed use patterns of azinphos methyl, based on the product labels registered to Bayer Corp., is presented in Table A (Appendix II). A tabular summary of the residue chemistry science assessments for reregistration of azinphos methyl is presented in Table B (Appendix III). The conclusions listed in Table B regarding the reregistration eligibility of azinphos methyl food/feed uses are based on the use patterns registered by the basic producer, Bayer Corp. When end-use product DCIs are developed (e.g., at issuance of the RED), they should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's labels.

ii. OPPTS GLN 860.1300: Nature of the Residue in Plants. The reregistration requirements for plant metabolism are fulfilled. Acceptable studies depicting the qualitative nature of the residue in or on apple, cotton, and potato have been submitted and evaluated. Based on these studies, it has been determined that the residue of concern in/on plant commodities is azinphos methyl *per se*. The current tolerance expression for plant commodities is appropriate.

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iii. OPPTS GLN 860.1300: Nature of the Residue in Livestock. The reregistration requirements for animal metabolism are fulfilled. Acceptable studies, depicting the qualitative nature of the residue in ruminant and poultry have been submitted and evaluated. The HED Metabolism Committee has determined that the residue of concern in animal commodities is azinphos methyl per se. Tolerances are currently expressed in terms of parent only for residues in/on fat, meat, and meat byproducts of cattle, goats, horses and sheep and in terms of parent and its metabolites in milk. The current tolerance for milk must be changed to regulation of the parent only.

iv. OPPTS GLN 860.1340: Residue Analytical Methods. Adequate analytical methodology is available for data collection and enforcement of tolerances of azinphos methyl. A gas chromatograph (GC)/flame photometric detection (FPD) method No. 69523 has undergone a successful Agency validation trial and is recommended by HED for inclusion in PAM, Vol. II. Using method No. 69523, residues are extracted with acetone/water, partitioned into chloroform, purified using gel permeation chromatography and silica gel, and analyzed by GC/FPD. The spectrophotometric methods listed in PAM, Vol. II are not considered specific and are to be replaced.

Data from analysis of azinphos methyl residues in plant and animal matrices have been collected using Method No. 69523 or modifications as well as the non-specific spectrophotometric methods.

v. OPPTS GLN 860.1360: Multiresidue Method Testing. The FDA PESTDATA database indicates that azinphos methyl is completely recovered using FDA Multiresidue Protocol A, with a special GC/HPLC, and Protocol D for non-fatty foods (PAM, Vol. I Sections 242.2 and 232.4).

vi. OPPTS GLN 860.1380: Storage Stability Data. Requirements for storage stability data are satisfied for purposes of reregistration. Residues of azinphos methyl are stable for 18-24 months in representative commodities in frozen storage.

vii. OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants. For purposes of reregistration, requirements for magnitude of the residue in plants are fulfilled for the following crops: alfalfa, almonds, apples, blackberries, blueberries, boysenberries, citrus fruits, cottonseeds, cranberries, cucumbers, grapes, loganberries, melons, onions, nectarines, peaches, pecans, pistachios, plums, pomegranates, raspberries, rye, strawberries, sugarcane, and tomatoes. Adequate field trial data depicting azinphos methyl residues following applications made according to the maximum or proposed registered use patterns have been submitted for these commodities. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Data on alfalfa will support the use on birdsfoot trefoil and clover, data on broccoli, cabbage and cauliflower will translate to brussel sprouts, data on peppers and tomatoes will translate to eggplant, data on plums will be used to

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support cherries, data on pecans will support filberts, and data on apples will support uses on pears and quinces. Additional data are forthcoming to fulfill outstanding requirements on walnuts.

IR-4 has submitted adequate field trial data to support the tolerances on broccoli. IR-4 has submitted field trial data in support of peppers (bell and non-bell), cabbage, cauliflower, broccoli, and succulent beans. These data are under review. The additional field trials were required in Regions 1, 5, and 12 for cauliflower. Alternatively, field trial data on cabbage conducted in Regions 1, 2, 3, 5, 6, and 10 may be done if the registrant desires a head and stem Brassica crop subgroup tolerance. Additional data from IR-4 are forthcoming to fulfill outstanding requirements on celery and spinach.

For purposes of reregistration, additional residue data are required on cotton gin byproducts. Data are required depicting azinphos methyl residues in/on cotton gin byproducts ginned from cotton harvested on the day after the last of multiple foliar applications of azinphos methyl at the maximum labeled rate and totaling 6 lb ai/A/season. The cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue from the ginning process. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials. Azinphos methyl residue data on cotton gin byproducts exist from previously conducted field trials. As an alternative to conducting new field trials, the registrant may identify and re-submit those data on cotton gin byproducts that were collected using acceptable harvesting techniques and analyzed using adequate gas chromatographic (GC) method(s) and which reflect the currently registered use pattern.

viii. OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed. The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for apple, citrus, cottonseed, grape, potato, sugarcane, and tomato. Based on the available processing studies, separate tolerances are only required for citrus oil, cottonseed hulls, and wet apple pomace.

A tolerance should be established for citrus oil. An adequate processing study indicated that residues concentrated 7.45x in orange oil. Applying the concentration factor to the highest average field trial (HAFT) residues for oranges of 1.5 ppm, the expected residue in orange oil would be 11.2 ppm. A tolerance of 15 ppm would be sufficient to cover residues in citrus oil.

A tolerance should be established for wet apple pomace. An adequate processing study on apples indicated that residues concentrated 2x in wet apple pomace. Applying this concentration factor to the HAFT residues for apples of 1.7 ppm, the expected residue in apple pomace would be 3.4 ppm. A tolerance of 4 ppm would be sufficient to cover residues in wet apple pomace.

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A tolerance should be established for cottonseed hulls. Residues concentrated 1.4x in cottonseed hulls. Applying this concentration factor to the HAFT residues for cottonseed of 0.5 ppm, the expected residue in cottonseed hulls would be 0.7 ppm. A tolerance of 1.0 ppm would be sufficient to cover residues in wet cottonseed hulls.

No processing study exists on rye grain or on any other small cereal grain. However, as residues on these crops were <0.01 ppm, one twentieth the tolerance, and the theoretical concentration factor is 10x, a processing study is not required.

ix. OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs. The maximum theoretical dietary intake of azinphos methyl by cattle is approximately 7 ppm, based on the diet calculated as follows:

Commodity	Tolerance (ppm)	Dry Weight (%)	% Beef Cattle Diet	Residues in Beef Cattle Diet (ppm)	% Diary Cattle Diet	Residues in Dairy Cattle Diet (ppm)
Almond hulls	5[1]	90	10	0.6	10	0.6
Alfalfa hay	5	89	60	3.4	60	3.4
Apple pomace (wet)	4 [b]	40	30	3	20	2
Cottonseed meal	0.5	88	--	--	10	0.06
Total				**7**		**6.06**
[1]Reassessed tolerance.			[2]New tolerance required.			

Residues of azinphos methyl analyzed by currently accepted GC/FPD methods were <0.01 ppm in all animal tissues and milk at all feeding levels from 11 to 77 ppm (up to 11x) (MRID 00030303, report nos. 66448, 66450, 66451). Data collected using the non-specific colorimetric (fluorescence) methods (MRID 00090126) are disregarded. Because residues were nondetectable in milk and animal tissues at feeding levels up to 11x, a 40 CFR §180.6(a)(3) situation exists (i.e., there is no reasonable expectation of detectable residues of azinphos methyl) for azinphos methyl residues in ruminant tissues and milk and the tolerances should be revoked.

Results from the poultry metabolism studies indicate that a 40 CFR §180.6(a)(3) situation exists for azinphos methyl residues in poultry tissues and eggs. Therefore tolerances are not needed on poultry commodities.

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x. OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, and Irrigated Crops. Azinphos methyl is presently not registered for direct use on potable water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

xi. OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments. Azinphos methyl is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

xii. OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops. Chemical Review Management System (CRMS) cites a 1990 confined rotational crop study (MRID 41393601) and a review by EFED dated 1/2/92; the study was judged supplemental. Azinphos methyl was extensively metabolized in soil following application. At 30 days after treatment, 20% of the soil total radioactive residue (TRR) was accounted for by azinphos methyl and seven degradates were identified, none of which retained an intact organophosphate structure. After 70 and 135 day^ of aging <10% of the soil radioactivity was the parent compound and at 181 days and thereafter azinphos methyl was below the LOQ in soil (<0.04 ppm). Commodities of kale, wheat, and beets planted at the 30-day plant-back interval did not contain detectable azinphos methyl residues. [^{14}C]Residues in edible commodities planted 30 days after soil treatment were identified as soil residues and conjugates thereof; the metabolite profile in rotated crops was similar to that seen in a metabolism study on cotton.

The current product labels prohibit planting root crops for which azinphos methyl is not registered within 6 months of treatment; a plant-back restriction of 30 days is specified for all other crops for which azinphos methyl is not registered. This plant-back restriction is adequate. No residues of concern are expected in rotated crops. Therefore, field rotational crop studies and potential tolerances on rotated crops are not required.

xiii. OPPTS GLN 860.1900: Field Accumulation in Rotational Crops. The EFED one-liner database included the following regarding a field rotational crop study:

> No residues were detected in grain, pod vegetables, or leafy vegetables planted 30 days after application of 8 lb ai/A.

The results of a confined rotational crop study indicate that residues of concern are not expected in rotated crops; therefore, field accumulation studies are not required.

xiv. Tolerance Reassessment/Codex Summary. Tolerances for residues of azinphos methyl in/on plant RACs are currently expressed in terms of azinphos methyl [40 CFR §180.154 (a) and (b)] or azinphos methyl and/or its metabolites [40 CFR §180.154a]. The HED Metabolism Committee has determined that the residue to be regulated is the parent, azinphos methyl. Food/feed additive tolerances have been established for residues of azinphos methyl in soybean oil [40 CFR §185.2225] and dried citrus pulp and sugarcane bagasse [40 CFR §185.2225].

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A summary of the azinphos methyl tolerance reassessment and recommended modifications in commodity definitions are presented in Table 5, below.

xv. Tolerances Listed Under 40 CFR §180.154 (a):

- Sufficient data are available to ascertain the adequacy of the established tolerances on all listed commodities that are to be supported except for walnuts.

- In accordance with 40 CFR §180.1 (h), the tolerance on peaches covers nectarines. Therefore, the individual tolerance on nectarines should be deleted.

- A tolerance for "caneberries" is recommended, concomitant with deletion of individual tolerances on blackberries, boysenberries, loganberries, and raspberries. The tolerance for caneberries should be increased to 8 ppm, based on residues of 7.6 ppm in/on a loganberry sample harvested 3 days following application to the lower portion of the cane at 1x (MRID 42076801; CBRS No. 9195, DP Barcode D172624, 8/27/92, B. Cropp-Kohlligian).

- The available data indicate that the tolerances established for almonds, grapes, and potatoes can be lowered to achieve compatibility with the corresponding Codex MRLs. Available data indicate that the 10.0 ppm tolerance for almond hulls can be lowered to 5.0 ppm. In addition, the tolerance for cranberries can be lowered to 0.5 ppm.

- As there are no registered uses on apricots, barley, dry beans, gooseberries, grass, kiwi fruit, oats, peas, soybeans, and wheat, the tolerances on these crops should be revoked. The following crops appear on current Bayer labels (see Table A), although the registrant has indicated that they do not intend to support these uses: artichoke, peppers, cabbage, Brassica, eggplant, and celery. However, as previously stated IR-4 will support peppers, brassica, cabbage, eggplant, and celery.

- The available data indicate that finite residues are not expected in animal tissues (refer to the discussion under OPPTS GLN 860.1480); therefore the tolerances on animal tissues should be revoked.

xvi. Tolerances Listed Under 40 CFR §180.154 (b):

- Sufficient data are available to ascertain the adequacy of the established tolerance with a regional registration on pomegranates.

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xvii. Tolerances Listed Under 40 CFR §180.154a:

- The available data indicate that finite residues are not expected in milk (refer to the discussion under OPPTS GLN 860.1480); therefore the tolerance for milk should be revoked and this section should be deleted.

xviii. Tolerances Listed Under 40 CFR §185.2225:

- The established food additive tolerance for soybean oil should be revoked, as there is no registered use on soybeans.

xix. Tolerances Listed Under 40 CFR §186.2225:

- The established tolerance for dehydrated citrus pulp should be revoked, as an adequate orange processing study did not show concentration in dried orange pulp.

- The established tolerance for sugarcane bagasse should be revoked, as this commodity is not considered a significant livestock feed item.

xx. New Tolerances Needed Under 40 CFR §180.154 (a):

- Residue data are required to determine a tolerance level for cotton gin byproducts.

xxi. New Tolerances Needed Under 40 CFR §186.2225:

- A tolerance should be established for citrus oil, based on a concentration factor of 7.45x.

- A tolerance should be established on wet apple pomace, based on a concentration factor of 2x. A tolerance of 1.0 ppm is needed for cottonseed hulls based on the 1.3x concentration factor and HAFT residues of 0.5 ppm.

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Table 5. Tolerance Reassessment Summary for Azinphos Methyl			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Tolerances listed under 40 CFR §180.154 (a):			
Alfalfa	2	2	
Alfalfa, hay	5	5	
Almonds	0.3	0.2	The U.S. tolerance can be lowered to harmonize with the corresponding Codex MRL.
Almonds, hulls	10	5	The U.S tolerance can be lowered to harmonize with the corresponding Codex MRL.
Apples	2	2	
Apricots	2	Revoke	No registered use.
Artichokes	2	Revoke	Not supported.[1]
Barley, grain	0.2	Revoke	No registered use.
Barley, straw	2	Revoke	No registered use.
Beans, dry	0.3	Revoke	No registered use.
Beans, succulent (snap)	2	TBD	
Birdfoot trefoil	2	2	
Birdfoot trefoil hay	5	5	
Blackberries, boysenberries, loganberries, raspberries	2	8	Residues of 7.6 ppm occurred from registered use on lower part of the cane with a 3-day PHI. *Caneberries*
Blueberries	5	5	
Broccoli	2	2	
Brussels sprout	2	2	
Cabbage	2	TBD	Data forthcoming from IR-4.
Cattle, fat	0.1	Revoke	40 CFR §180.6(a)(3) situation exists.
Cattle, mbyp	0.1	Revoke	
Cattle, meat	0.1	Revoke	
Cauliflower	2	TBD	Data forthcoming from IR-4.
Celery	2	TBD	Data forthcoming from IR-4.
Cherries	2	2	
Citrus fruits	2	2	
Clover	2	Revoke	No registered use.
Clover, hay	5	Revoke	No registered use.
Cottonseed	0.5	0.5	

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Table 5. Tolerance Reassessment Summary for Azinphos Methyl			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Crabapples	2	2	
Cranberries	2	0.5	The U.S tolerance can be lowered to harmonize with the corresponding Codex MRL.
Cucumbers	2	2	
Eggplants	0.3	TBD	IR-4 submitted data in support.
Filberts	0.3	0.3	
Goats, fat	0.1	Revoke	40 CFR §180.6(a)(3) situation exists
Goats, mbyp	0.1	Revoke	
Goats, meat	0.1	Revoke	
Gooseberries	5	Revoke	No registered use.
Grapes	5	4	The U.S tolerance can be lowered to harmonize with the corresponding Codex MRL.
Grass, pasture (green)	2	Revoke	No registered use.
Grass, pasture, hay	5	Revoke	No registered use.
Horses, fat	0.1	Revoke	40 CFR §180.6(a)(3) situation exists
Horses, mbyp	0.1	Revoke	
Horses, meat	0.1	Revoke	
Kiwi fruit	10	Revoke	No registered use.
Melons	2	2	
Nectarines	2	Revoke	Covered by the tolerances for peaches.
Oats, grain	0.2	Revoke	No registered use.
Oats, straw	2	Revoke	No registered use.
Onions	2	2	
Parsley, leaves	5	5	
Parsley, roots	2	2	
Peaches	2	4	The U.S. tolerance can be increased to harmonize with the corresponding Codex MRL.
Pears	2	2	
Peas, black-eyed	0.3	Revoke	No registered use.
Pecans	0.3	0.3	
Peppers	0.3	TBD[2]	IR-4 submitted data in support.
Pistachios	0.3	0.3	
Plums (fresh prunes)	2	2	

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Table 5. Tolerance Reassessment Summary for Azinphos Methyl			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment/*Correct Commodity Definition***
Potatoes	0.3	0.2	The U.S tolerance can be lowered to harmonize with the corresponding Codex MRL.
Quinces	2	2	
Rye, grain	0.2	0.2	
Rye, straw	2	2	
Sheep, fat	0.1	Revoke	40 CFR §180.6(a)(3) situation exists.
Sheep, mbyp	0.1	Revoke	
Sheep, meat	0.1	Revoke	
Soybeans	0.2	Revoke	No registered use.
Spinach	2	TBD	Data forthcoming from IR-4
Strawberries	2	2	
Sugarcane	0.3	0.3	
Tomatoes (pre- and post-H)	2	2	*Tomatoes*
Walnuts	0.3	TBD	Additional data are forthcoming.
Wheat, grain	0.2	Revoke	No registered use.
Wheat, straw	0.2	Revoke	No registered use.
Tolerances listed under 40 CFR §180.154 (b)			
Pomegranates	0.1	0.1	
Tolerances listed under 40 CFR §180.154a			
Milk	0.04	Revoke	40 CFR §180.6(a)(3) situation exists.
Tolerances listed under 40 CFR §185.2225			
Soybean oil	1	Revoke	No registered use.
Tolerances listed under 40 CFR §186.2225			
Dried citrus pulp	5	Revoke	Residues do not concentrate in this fraction.
Sugarcane bagasse	1.5	Revoke	Not a significant livestock feed item.
Cotton gin byproducts	none	TBD	Residue data required.
Citrus oil	none	15	
Tolerances needed under 40 CFR §186.2225			
Apple, wet pomace	none	4	
Cottonseed hulls	none	1	

[1]CBRS No. 16871, DP Barcode D222840, 6/28/96, F. Fort.

[2]TBD = To be determined. Tolerance cannot be determined at this time because additional data are required or are under review.

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xxiii. Codex Harmonization. The Codex Alimentarius Commission has established maximum residue limits (MRLs) for azinphos methyl residues in/on various plant and animal commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table 6.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs: The U.S. tolerances for almonds, grapes, and potatoes can be decreased and the tolerance for peaches can be increased to harmonize with the Codex MRLs.

Table 6. Codex MRLs for Azinphos Methyl and Applicable U.S. Tolerances

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	**MRL (mg/kg)**	**Step**		
Alfalfa forage (green)	2	CXL	2	
Almonds	0.2	CXL	0.2	
Apricot	2	CXL	Revoked	No registered use in the U.S.
Broccoli	1	CXL	2	Additional data are required to assess the U.S. tolerance.
Brussels sprouts	1	CXL	2	Additional data are required to assess the U.S. tolerance.
Celery	2	CXL	TBD	IR-4 supported.
Cereal grains	0.2	CXL	0.2 (rye)	
Citrus fruit	2	CXL	2	
Cotton seed	0.2	CXL	0.5	The registered U.S. use pattern precludes lowering the tolerance to harmonize with the Codex MRL.
Fruits (except as otherwise noted)	1	CXL	2-5	The registered U.S. use patterns preclude lowering tolerances to harmonize with Codex MRLs.
Grapes	4	CXL	4	
Kiwifruit	4	CXL	Revoked	No registered use in U.S.
Melons, except watermelon	2	CXL	2	
Pea vines (green)	5	CXL	none	
Peach	4	CXL	4	
Potato	0.2	CXL	0.2	
Soya bean forage (green)	2	CXL	none	
Soya bean (dry)	0.2	CXL	Revoked	
Sunflower seed	0.2	CXL	none	

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Table 6. Codex MRLs for Azinphos Methyl and Applicable U.S. Tolerances

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Vegetables (except as otherwise noted)	0.5	CXL	2-5	The registered U.S. use patterns preclude lowering tolerances to harmonize with Codex MRLs.

b. Dietary Risk Assessment (Food Sources)

i. Acute Dietary Risk. The Agency uses a tiered approach to perform acute dietary exposure and risk assessments as outlined in the memorandum dated June 13, 1996 (D. Edwards). This approach allows the Agency to conserve resources. The results of the tiered sequence of dietary assessments conducted for this risk assessment are provided below.

Tier 1. HED conducted a detailed acute dietary risk analysis estimating the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis included all currently registered uses of azinphos methyl. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of azinphos methyl in the commodity supply. The assessment assumes tolerance level residues and that 100% of the crop is treated with azinphos methyl. The LOAEL from the acute neurotoxicity study (1 mg/kg/day) was used to calculate the acute dietary risk.

The Margin of Exposure (MOE) is a measure of how close the exposure comes to the NOAEL (the highest dose at which no effects were observed in the toxicology test), and is calculated as the ratio of the NOAEL to the exposure [MOE = NOAEL (mg/kg/day) ÷ Exposure (mg/kg/day)]. Generally, acute dietary MOEs greater than 100 tend to cause no concern when results are compared to animal-derived data. However, in the case of azinphos methyl, an additional UF of 3 is required for the acute dietary risk assessment, because the acute neurotoxicity study did not identify a NOAEL. No additional uncertainty factor for special sensitivity in infants and children was warranted. In place of a NOAEL, the LOAEL was used to calculate risk, and the ratio of the LOAEL to the exposure is compared to a MOE of 300 to account for the lack of a NOAEL from the critical acute neurotoxicity study. At a tier 1 level of analysis, using the high-end exposure, presently registered commodities result in the following MOEs at the 95th percentile of exposure. The results are given in Table 7.

Table 7. Acute Dietary Analysis Assuming Tolerance Level Residues and 100% of Crop Is Treated @ 95th Percentile of Exposure			
Population Subgroups	**High-End Exposure (mg/kg/day)**	**Percent Acute RfD**	**MOE**
U.S. General Population	0.14	4670%	7
Infants <1 year	0.3	10,000%	3
Children (1-6 years old)	0.3	10,000%	3
Females (13+ years)	0.08	2666%	12.5
Males (13+ years)	0.06	2000%	17

The results of this tier 1 analysis indicated that further refinement to the exposure and risk analysis was necessary.

Tier 2. For clarity and brevity, the results of the most-refined, probabilistic acute dietary assessment conducted by HED are provided below and compared to the registrant's most recently submitted acute probabilistic dietary assessment. HED skipped the tier 2 level assessment for azinphos methyl and proceeded directly to tier 3.

Tier 3. OPP is currently utilizing both FDA's (Market Basket Survey) and USDA's (Pesticide Data Program (PDP)) pesticide residue monitoring data on composited samples of commodities for which this information is available when conducting chronic dietary risk assessments. However, for the acute dietary analysis, monitoring data can only be used directly (as is) for those commodities which are considered blended, i.e., for food forms that are typically mixed prior to consumption [grains (e.g. rice) and grain products, oils, sugars, most juices, tomato products (paste, puree, and juice), dried potatoes, soybeans, peanuts, mint oils, milk, wine, and sherry]. Monitoring data cannot be used directly (as is) for commodities which are considered as a "single serving size," or cannot be assumed to be mixed during processing; e.g., apples, oranges, pears, bananas, and potatoes. The reason for this is that monitoring data provided to EPA are composited and therefore not reflective of a single serving exposure which the acute risk is based on. This therefore severely limits the usage of this data. In an effort to utilize monitoring data in an acute dietary probabilistic analysis, a statistical model has been devised where we can use composite samples in an acute probabilistic dietary assessment. In addition, PDP performed an analyis for residues of azinphos methyl on individual "single servings" of pears. These data became available at the time of this risk assessment and were used in the acute dietary analysis. These data were used directly for pears and translated directly to apples, quinces, and crabapples.

The statistical model produces a lognormal distribution that describes the residues on individual commodities provided there are a significant number of samples with detections (more than 30). To produce the lognormal distribution that describes the concentration in single servings, it's necessary to estimate its mean value and the standard deviation. The mean value of the composite samples equals the mean value of the single serving. A high estimate of the standard deviation is then calculated by multiplying the composite sample's standard deviation by the square root of the number of units in the composite. Distributions are then generated. A combined Log-Normal distribution was assembled for commodities for which there were multiple years of PDP data. The next step in completing the assessment was the generation of data points from these distributions. These data points were then fed into the dietary exposure model for risk analysis. Percent crop treated information was incorporated and the ratio between detects and non-detects reported in the PDP reports remained intact. Translation of decomposited data from commodities with PDP data to commodities for which there were no PDP data available was done as appropriate.

PDP data were available and decomposited for peaches, only. The decomposited data on peaches were translated to other stone fruits (i.e., plums). For other crops included in the dietary assessment, but without PDP data, the existing PDP data were translated to appropriate crops within a crop grouping, i.e., PDP data for oranges were translated to other citrus crops, PDP data on spinach was translated to other leafy vegetables and the subgrouping of Brassica. FDA data were used for all berry crops included in the dietary analysis except strawberries and cranberries. Field trial data were used for the remaining crops. It should be noted that the following commodities were not used in the analysis but have been determined to be supported by the registrant, IR-4, or under 24(c) Special Local Need petitions in the HED chapter of the azinphos methyl RED: parsley, sugarcane, and pomegranates.

Because a 40 CFR 180.6(a)(3) situation exists for azinphos methyl residues in livestock commodities (no expectation of finite residues) and current tolerances for residues of azinphos methyl on ruminant tissues and milk have been recommended for revocation, livestock commodities were not considered in this analysis.

Residue information used in both the registrant and HED conducted acute dietary analysis is summarized in Table 5 of Attachment 1. Attachment 1 also lists the Residue Distribution Files used in this analysis and referred to in Table 5.

The results of this analysis are given in Table 8 below. The table provides a side-by-side comparison of the results of the registrant's most recently submitted probabilistic acute dietary assessment (MRID 446862-10) and HED's assessment using "decomposited" monitoring data as described above.

Table 8. Probabilistic Acute Dietary Analysis Results at the 99.9th Percentile of Exposure

Population Subgroup	Bayer Analysis		HED Analysis		
	Exposure	MOE[1]	Exposure	MOE[1]	% aRfD[2]
US population	0.005062	197	0.001781	561	59%
All infants (< 1 year)	0.00841	118	0.003003	332	100%
Nursing infants (< 1 year)	0.008483	117	0.003632	275	121%
Non-nursing infants (< 1 year)	0.008336	119	0.002234	447	74%
Children (1-6 years)	0.008943	111	0.003913	255	130%
Children (7-12 years)	0.006206	161	0.002704	369	90%

[1] The Margin of Exposure (MOE) considered to be above HED's level of concern is 300 for acute dietary exposure and risk estimates.

[2]The acute RfD used is 0.003 mg/kg/day.

Based on HED's analysis, which HED believes provides the most refined assessment to date, risk estimates exceed HED's levels of concern for two subgroups at the 99.9th percentile of exposure: nursing infants less than 1 year old, and children 1 to 6 years of age (Table 8). The risk estimates for these two subgroups are 121% and 130% of the acute RfD, respectively, as shown above. Risk estimates for all other subgroups are equal to or below 100% of the acute RfD, and therefore below HED's level of concern. Risk estimates at the 99th percentile of exposure are below HED's level of concern for all population subgroups. [Note: For the specific differences between the registrant's and HED's analyses see HED memorandum, F. Fort, 2/17/99, D253314.]

HED is also performing a critical exposure contribution analysis to determine if there was any individual with excessive consumption patterns that would affect the risk estimates. This analysis is not yet completed.

In summary, the HED acute dietary analysis includes the following components:

- Single serving PDP monitoring data (for pears) were used directly, including ½ the LOD and % crop treated. These data were translated to apples, quinces and crabapples with their corresponding % crop treated incorporated. In some previous assessments, a distribution of single-serving residues derived from composite samples were used where data were adjusted to reflect single servings (decomposition method).

- "Decomposited" monitoring data (USDA and FDA sources) to establish a distribution of residues for single-serving of peaches in the probabilistic acute dietary analysis. These decomposited data were then translated to other stone fruits (i.e., plums).

- Residue distributions for azinphos methyl that include the most up-to-date, approved percent crop treated data to "zero-out" non-detectable residues representing that portion of the crop not treated with azinphos methyl.

- Inclusion of the remaining non-detectable residues as ½ the limit of detection (LOD) or ½ the limit of quantitation (LOQ), whichever is appropriate.

- The determination that commodities the size of or smaller than a strawberry (i.e., nuts and berries) will be considered "co-mingled" commodities and are therefore treated as blended commodities (and as such composited monitoring data is used for these commodities).

- For those commodities which are considered partially blended, small berries, PDP monitoring data was used directly incorporating % crop treated. In the earlier assessment, no adjustment for % crop treated was included.

- For canned and boiled apples, peaches, pears and plums, an average of the PDP monitoring data incorporating % crop treated and ½ the limit of detection (LOD) for non-detects was used.

- FDA monitoring data were incorporated for tart and sweet cherries. In previous assessments field trial residue data were used.

- Pistachio nuts, cottonseed meal and cottonseed oil were included in the assessment. These commodities were previously excluded.

- Saucing processing/reduction factor provided by the registrant was included for boiled apples (applesauce). EPA used these data in their revised analysis; however, raw data allowing the Agency to verify these values must be submitted.

- Adjustments were made to account for the differences in % crop treated for sweet and tart cherries and processed and unprocessed tomatoes.

- Washing/processing factors, when available for a variety of processed commodities.

- Excludes meat, milk, poultry and egg commodities from the diet based on a 180.6(a)3 categorization.

ii. Chronic Dietary Risk. The chronic dietary exposure estimate is used to calculate the lifetime risk of consuming an average amount of azinphos methyl residues in the diet. The Dietary Risk Estimate System (DRES) analysis used to determine this exposure and risk used percent-crop-treated data and anticipated residue data to calculate the Anticipated Residue Concentration (ARC) for the general U.S. population and 22 population subgroups. This is not a worst-case estimate for chronic dietary exposure and risk, but a highly refined assessment using either FDA monitoring data or field trial data adjusted with percent crop-treated information. The appropriate toxicological endpoint used for a chronic dietary exposure and risk analysis is the RfD. As previously defined, the RfD is 0.0015 mg/kg/day. Existing tolerances (i.e., published tolerances) result in an ARC which represents 13% of the RfD for the U.S. general population. The most highly exposed subgroup, Non-Nursing Infants (<1 year old), occupies 54% of the RfD and Children (1-6 years old) occupies 33% of the RfD. Based on the risk estimates calculated in this analysis, it appears that the chronic risk contributed to the dietary risk from the registered uses of azinphos methyl, is not of concern.

c. Exposure from Drinking Water

There is no established Maximum Contaminant Level (MCL) for residues of azinphos methyl in drinking water. No health advisory levels for azinphos methyl in drinking water have been established.

i. Ground water (modeling/monitoring). A screening level assessment (tier 1) that provides estimates of the concentration of azinphos methyl in ground water was conducted. This tier 1 assessment used SCI-GROW, an empirical model based on actual ground-water monitoring data from small-scale prospective ground-water monitoring studies, to estimate upper bound concentrations of a chemical in vulnerable ground water. The SCI-GROW model estimated a 90-day peak average concentration of 0.44 ppb for azinphos methyl in ground water. This value was compared to drinking water levels of comparison (DWLOCs) calculated for both acute and chronic effects of azinphos methyl. Estimates of the average concentration of azinphos methyl in ground water indicate that chronic exposure through drinking water will be infrequent. Estimated average concentrations in ground water (0.44 ppb) do not exceed drinking water levels of comparison (DWLOCs) for chronic exposure for the general U.S. population, females (13+), children (1-6 years old), and infants, non-nursing (<1 year). The DWLOCs for chronic exposure for these subpopulations are: 45, 39, 10, and 7 ppb, respectively.

There is limited data from one study report suggesting that azinphos methyl can reach ground water if used in areas with karst terrain. Specifically, the EFED reports detections of azinphos methyl of approximately 75 ppb in ground water in an area underlain by karst terrain. Karst topography is associated with land form features such as caves and sinkholes. Karst is found throughout the U.S. including areas of Florida, Kentucky, Pennsylvania, Missouri, Iowa, New Mexico, and Virginia There are strong connections between surface water and ground water in karst regions. While the QA/QC information that are necessary to assure that the monitoring data is of high quality are not available and the data are described in less detail than is desirable, we have no reason to doubt their validity. Because recharge of groundwater in very rapid in karst, the results of the study are plausible and are cause for substantial concern. This concern extends beyond the two counties that were sampled in this study to other karst regions where azinphos methyl is used. The SCI-GROW model estimates (described below) are not representative of karst hydrology, but rather represent shallow ground water under sandy soils in areas with substantial recharge. Thus, while SCI-GROW represents a good screening estimate on what would be expected in most ground water, it does not provide a good screening estimate for ground water in karst terrain. As noted above, karst aquifers will have a high pH and azinphos methyl is not expected to persist under these conditions. Consequently our concern is for acute risk rather than chronic risk. These data are sufficient to warrant additional monitoring in karst regions in order to better characterized azinphos methyl occurrence in these aquifer systems.

For the purposes of this assessment, estimates of concentrations of azinphos methyl, only, in ground water were considered. Soil aerobic metabolism studies (see EFED RED chapter) indicate the presence of the oxygen analog of azinphos methyl in small amounts in soil (5% of applied radioactivity). However, these data are inconclusive as to whether the oxygen analog is present in ground water.

ii. Surface water (modeling/monitoring). Model estimates for maximum concentrations of azinphos methyl in surface water were not used for acute exposure assessment because the exposure to azinphos methyl residues in food alone exceed HED's level of concern for acute dietary risk. Any additional exposure to azinphos methyl through drinking water would only cause acute risk estimates to further exceed our level of concern.

Conservative model estimates of average concentrations (annual means) in surface water from the PRZM/EXAMS model range from 13.4 ppb to 0.08 ppb depending on the crop/use rate simulated. The two highest yearly average (annual mean) concentrations predicted were 13.4 and 7.2 ppb. These concentration estimates resulted from maximum label application rates and are based on simulations for cotton and peaches, respectively. When the cotton simulation is based on reduced application rates proposed by the registrant and typical use rates, the average concentrations predicted by the model are 6.7 ppb and 1.1 ppb, respectively. When the peaches simulation is based on typical use rates, the average concentration predicted by the model is 3.0 ppb. The maximum concentration of azinphos methyl in surface water estimated by PRZM/EXAMS was 88 ppb, based on high-exposure scenarios for cotton uses.

Monitoring data though sparse and not representative of drinking water are available for comparison with model estimates of surface water concentrations. US EPA's STORET database contains 15 detections out of 1123 samples at 653 sites. Note, that constitutes less than 2 samples per site with detections of azinphos methyl. The maximum detection was 3 µg/L. Detection limits varied widely, from 0.001 to 2 µg/L. US Geological Survey monitoring studies (1993-1997) have detected azinphos methyl infrequently in surface waters at low levels (maximum concentrations detected was 1 ppb). However, the percentage recovery of residues of azinphos methyl from the analytical method used is poor (13%) and the data cannot be used reliably for exposure assessment. Sampling for azinphos methyl by the state of Florida in the southern part of the state resulted in no detections of the chemical.

For the purposes of this assessment, estimates of concentrations of azinphos methyl, only, in surface water were considered. Soil aerobic metabolism studies (see EFED RED chapter) indicate the presence of the oxygen analog of azinphos methyl in small amounts in soil (5% of applied radioactivity). However, these data are inconclusive as to whether the oxygen analog is present in surface water.

d. Drinking Water Risk

Currently, HED uses drinking water levels of comparison (DWLOCs) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). It is used as a point of comparison against the model estimates to determine if the estimated concentration is of concern. A DWLOC may vary with drinking water consumption patterns and body weights for specific subpopulations. The Agency has calculated drinking water levels of concern for acute and chronic exposures to azinphos methyl in drinking water for the general U.S. population, females (13+), children (1-6 years old), and non-nursing infants (<1 year old), respectively.

In effect, for acute exposure to azinphos methyl, the drinking water level of comparison (DWLOCs) for all subpopulations is zero. Because the exposure to residues from food alone for at least one subgroup exceeds HED's level of concern for acute dietary exposure, any additional exposure to azinphos methyl in drinking water would lead to risk estimates that further exceed HED's level of concern. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from the DRES/DEEM analysis) was subtracted from the ratio of the acute NOAEL to the target MOE or the acute RfD to obtain the acceptable acute exposure to azinphos methyl in drinking water. DWLOC values were calculated using default body weights and consumption values (70 kg for adult males, 60 kg for adult females, and 10 kg for children, and drinking water consumption figures of 2 L/day for adults and 1 L/day for children).

For chronic (non-cancer) exposure to azinphos methyl, the drinking water levels of comparison (DWLOCs) are: 45, 39, 10, and 7 ppb for the subpopulations listed above, respectively. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES/DEEM) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to azinphos methyl in drinking water. DWLOC values were then calculated using default body weights and consumption values described above. A comparison of DWLOC values for acute and chronic risk to estimated concentrations of azinphos methyl in ground and surface waters is given in Table 9 below.

Table 9. Comparison of DWLOC Values to Model Estimates of Azinphos Methyl Concentrations in Surface and Ground Waters

Population Group	DWLOC (ppb) for Acute Assessment	DWLOC (ppb) for Chronic Exposure Assessment	Ground Water[1] Concentration Estimate (ppb)	Surface Water[2] Concentration Estimate (ppb)	
			max. & avg.	max.	avg.
General U.S./Hispanic	0	45	0.44	88	13.4
Females (13-19 years old)	0	39	0.44	88	13.4
Children (1-6 years old)	0	10	0.44	88	13.4
Infants, non-nursing (<1 year old)	0	7	0.44	88	13.4

[1]For ground water a 90-day average concentration is both the maximum and minimum concentration estimate and are considered the same for purposes of comparison against the DWLOC values.

[2]Highest annual average based on maximum label rates for cotton.

The estimated maximum concentrations of azinphos methyl in ground water (from SCI-GROW) is 0.44 ppb and in surface water (from PRZM/EXAMS) is 88 ppb. These estimates of azinphos methyl in ground and surface water would be used for acute exposure assessments. However, as stated above, the exposure to azinphos methyl from food sources alone exceeds HED's levels of

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concern for acute dietary risk, and any additional exposure through drinking water would only result in aggregate risk estimates that further exceed HED's level of concern.

Based on the concentration estimates of azinphos methyl in ground and surface water used in this analysis, the chronic exposure from azinphos methyl in the diet and in drinking water from registered uses of azinphos methyl, is not of concern. All concentration estimates of azinphos methyl in surface water from all use scenarios modeled indicate that chronic exposure from azinphos methyl in drinking water from registered uses of azinphos methyl, is not of concern, with the exception of a high-exposure, cotton-use-scenario using maximum label rates (see EFED RED chapter). Based on the upper-bound concentration estimate (13.4 ppb) of azinphos methyl in surface water from this specific use, there may be a potential concern. However, the registrant has submitted labels with fewer applications resulting in lower use rates on cotton.

The drinking water risk assessment can be refined to reflect the lowered rates. It is anticipated that this label change on cotton will reduce any potential risk estimate based on the existing label rates on cotton.

Based on its physical-chemical properties, residues of azinphos methyl are not expected to persist long enough in either ground- or surface-water-sourced drinking water to pose a chronic exposure scenario of concern; however, additional monitoring data on finished drinking water are needed to more accurately characterize the exposure suggested by the models and monitoring data.

4. Occupational and Residential Exposure and Risk Characterization

a. Use Patterns and Formulation Summary

Azinphos methyl is formulated as a liquid (10.0 to 34.9 percent active ingredient), a manufacturing product (88.1 percent active ingredient), and a wettable powder (35.0 to 54.9 percent active ingredient). Some wettable powder formulations are contained in water-soluble packaging. It is registered for use on a variety of terrestrial food/feed and non-food crops. At this time, products containing azinphos methyl are intended only for agricultural uses. There are no registered residential uses of azinphos methyl. Therefore, no exposure or risk calculations for residential uses are warranted. Azinphos methyl is a restricted use pesticide (RUP).

The following equipment is used to apply azinphos methyl: aircraft (both fixed-wing and helicopters), chemigation equipment, groundboom sprayer, airblast sprayer, low pressure handwand, and high pressure sprayer.

b. Applicator, Mixer-Loader, Handler Exposure and Assumptions

Short-term and intermediate-term dermal and inhalation exposure assessments were made using Pesticide Handlers Exposure Database (PHED) Version 1.1 surrogate data. No chemical-specific handler data were submitted. Fourteen major exposure scenarios were identified. For each scenario, exposures were determined for one or more crops, which were chosen to be representative of the typical range of the amount of active ingredient handled daily (ie., combination of application rate and area treated). While some larger application rates appear on some labels, it is believed that the rates used are more realistic for assessment purposes. Use of the higher rates might change the results in some cases, but not substantially. The treatment scenario (specific crops, application rates, and acres treated) used for each of 14 major exposure scenarios identified are given below:

(1a) Mixing/loading liquids for aerial/chemigation application (cotton treated with 0.13 - 0.75 lb ai/A and tomatoes treated with 0.375 - 1.5 lb ai/A, 350 acres treated for each scenario);

(1b) Mixing/loading liquids for groundboom application (potatoes treated with 0.375 - 0.75 lb ai/A over 80 acres, and tomatoes treated with 0.375 - 1.5 lb ai/A over 50 acres);

(1c) Mixing/loading liquids for airblast sprayer application (pecans treated with 1.5 - 2 lb ai/A, citrus treated with 1.25 - 2 lb ai/A, grapes treated with 0.75 - 1 lb ai/A, apples treated with 0.5 - 1 lb ai/A, and stone fruits treated with 0.875 - 2 lb ai/A, 20 acres treated for all scenarios);

(2a) Mixing/loading wettable powders for aerial application/chemigation irrigation (alfalfa treated with 0.25 - 0.5 lb ai/A, tomatoes treated with 0.375 - 1.5 lb ai/A, over 350 acres) ;

(2b) Mixing/loading wettable powders for groundboom application (potatoes treated with 0.375 - 0.75 lb ai/A over 80 acres, and tomatoes treated with 0.375 - 1.5 lb ai/A over 50 acres);

(2c) Mixing/loading wettable powders for airblast sprayer application (almonds treated with 1.5 - 2 lb ai/A, citrus treated with 1.25 - 2 lb ai/A, grapes treated with 0.75 - 1 lb ai/A, apples treated with 1 - 1.5 lb ai/A, and stone fruits treated with 0.875 -2 lb ai/A, 20 acres treated for each scenario);

(3) Applying sprays with fixed-wing aircraft (cotton treated with 0.13 - 0.75 lb ai/A and tomatoes treated with 0.375 - 1.5 lb ai/A, both scenarios over 350 acres);

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(4) Applying sprays with helicopter (cotton and tomatoes with same treatment scenario as in (3) above) ;

(5) Applying sprays using a groundboom sprayer (potatoes treated with 0.375 - 0.75 lb ai/A over 80 acres, and tomatoes treated with 0.375 - 1.5 lb ai/A over 50 acres);

(6) Applying sprays using an airblast sprayer (same treatment scenario as in (2c) above);

(7) Mixing/loading/applying sprays using a low pressure hand wand, spot treatment (ornamentals treated with 0.01 - 0.04 lb ai/gal. at 40 gallons);

(8) Mixing/loading/applying sprays using a high pressure hand wand, greenhouse (ornamentals treated with 0.01 - 0.04 lb ai/gal. at 1000 gallons);

(9*) Mixing/loading/applying sprays using a backpack sprayer, spot treatment (same scenario as (7) above);

(10*) Flagging during aerial application, sprays (cotton treated with 0.13 -0.75 lb ai/A over 350 acres).

* *On the most recently approved azinphos methyl labels, exposure scenarios (9) and (10) for application with backpack sprayers, and flagging during aerial application, respectively, have been prohibited.*

Table 10 provides short-term and intermediate-term dermal exposure and risk estimates for each of the 14 major exposure scenarios. Table 11 provides short-term and intermediate-term inhalation exposure and risk estimates for each of the 14 major exposure scenarios. A range of risks (MOEs), based on the maximum application rates of representative crops, is given for each of the scenarios with baseline exposure, exposure with additional protective clothing (PPE), and with engineering controls. For the baseline exposure, the worker is assumed to be wearing long pants, long sleeve shirt, no gloves, and there is open mixing/loading, and an open cab tractor. Additional PPE includes a double layer of clothing and gloves (used in scenarios 1,2,5,6,7,8, and 9), or include a double layer of clothing, only (scenario 10). The engineering controls varied for each scenario as follows:

Scenario 1:	Closed mixing system, single layer of clothing with chemical resistant gloves.
Scenario 2:	Water soluble packets no gloves.
Scenario 3 and 4:	Enclosed cockpit, single layer clothing, no gloves.
Scenario 5:	Enclosed cab, single layer clothing no gloves.

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Scenario 6: Enclosed cab, single layer clothing and chemical resistant gloves.
Scenario 10: Enclosed cab, single layer clothing no gloves.

Potential daily exposure is calculated using the following formula:

Daily Exp. (mg ai/day) = Unit Exp. (mg ai/lb ai) x Max. Appl. Rate (lb ai/acre) x Max. Area Treated (acres/day)

These calculations of daily exposure to azinphos methyl by handlers are used to calculate the daily dose to those handlers.

The daily dose is calculated using the following formula:

Daily Dose (mg ai/kg/day) = Daily Exp. (mg ai/day)/ body weight (kg)

These calculations of daily dose of azinphos methyl received by handlers are used to assess the dermal risk to those handlers. The short-term and intermediate-term MOEs were calculated using the following formula:

MOE = NOAEL (mg/kg/day)/ Daily Dose (mg/kg/day)

c. Occupational Risk Assessment/Characterization

i. Risk from Dermal and Inhalation Exposures. These calculations of daily dose of azinphos methyl by handlers are used to assess the risk to those handlers. For the short-term dermal risk assessment, a NOAEL of 0.56 mg/kg/day from a dermal absorption/toxicity study in rats was used along with a 70 kg body weight. For the short-term dermal assessment, no dermal absorption factor was used because the dose is a dermal NOAEL from a dermal study.

For the intermediate-term dermal risk assessment, an equivalent dermal dose of 0.36 mg/kg/day was derived by using the NOAEL from a one year oral toxicity study in dogs (0.149 mg/kg/day) and applying a dermal absorption factor (0.42) from a dermal absorption/toxicity study. The inhalation risk assessment used a NOAEL of 0.32 mg/kg/day* and a 70 kg body weight. No inhalation absorption data are available, therefore 100 percent absorption was assumed.

**NOTE: The inhalation endpoint (0.0012 mg/L) taken directly from the subchronic inhalation study in rats, was converted for use in the inhalation risk assessments through the following equation: [(0.0012 mg/L/day) (8.46 L/hr.) (6 hrs.) ÷ (0.190 kg)] = 0.32 mg/kg/day. The 0.190 kg is the body weight of the test animal (rat).*

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Table 10 below provides short-term (based on a NOAEL of 0.56 mg/kg/day) and intermediate-term (based on an equivalent dermal dose of 0.36 mg/kg/day) dermal risk estimates for the 14 scenarios.

Table 10. Short- and Intermediate-Term Dermal Risk Estimates for Mixer/Loader, Handlers of Azinphos Methyl

Exposure Scenario	Dose Range (mg/kg/day)	MOE Range		Dose Range (mg/kg/day)	MOE Range		Dose Range (mg/kg/day)	MOE Range	
		short-term	interm-term		short-term	interm-term		short-term	interm-term
	Unit of Exposure: Baseline (2.9 mg/ lb ai)			Unit of Exposure: Additional PPE (0.025 mg/lb ai)			Unit of Exposure: Eng. Controls (0.009 mg/lb ai)		
1(a)	10.9 - 21.8	All <1	All <1	0.1 - 0.19	3 - 6	2 - 4	0.006 - 0.0675	8 - 93	5 - 60
1(b)	2.5 - 3.1	All <1	All <1	0.021 - 0.027	21 - 27	13 - 17	0.008 - 0.01	56 - 70	36 - 45
1(c)	0.8 - 1.7	All <1	All <1	0.007 - 0.014	40 - 80	26 - 51	0.0025 - 0.005	112 - 224	72 - 140
	Unit of Exposure: Baseline (3.8 mg/lb ai)			Unit of Exposure: Additional PPE (0.089 mg/lb ai)			Unit of Exposure: Eng. Controls (0.02 mg/lb ai)		
2(a)	9.5 - 28.5	All <1	All <1	0.22 - 0.67	0.6 - 3	< 2	0.05 - 0.15	3 - 11	2 - 7
2(b)	3.3 - 4.1	All <1	All <1	0.08 - 0.10	6 - 7	3 - 4	0.02	28	18
2(c)	1.1 - 2.2	All <1	All <1	0.025 - 0.05	11 - 22	14 - 7	0.006 - 0.01	56 - 93	36 - 60
	Unit of Exposure: Baseline (mg/lb ai)			Unit of Exposure: Additional PPE (mg/lb ai)			Unit of Exposure: Eng. Controls (0.005 mg/lb ai)		
3	See Eng. Control	See Eng. Controls		See Eng. Controls	See Eng. Controls		0.02 - 0.038	15 - 28	9 - 18
	Unit of Exposure: Baseline (mg/lb ai)			Unit of Exposure: Additional PPE (mg/lb ai)			Unit of Exposure : Eng. Controls (0.0021 mg/lb ai)		
4	See Eng. Control	See Eng. Controls		See Eng. Controls	See Eng. Controls		0.008 - 0.016	35 - 70	23 - 45
	Unit of Exposure: Baseline (0.015 mg/lb ai)			Unit of Exposure: Additional PPE (0.01 mg/lb ai)			Unit of Exposure: Eng. Controls (0.0067 mg/lb ai)		
5	0.013 - 0.016	35 - 43	23 - 28	0.009 - 0.011	51 - 62	33 - 40	0.006 - 0.007	80 - 93	51 - 60
	Unit of Exposure: Baseline (0.36 mg/lb ai)			Unit of Exposure: Additional PPE (0.122 mg/lb ai)			Unit of Exposure: Eng. Controls (0.016 mg/lb ai) (gloves)		
6	0.10 - 0.21	2 - 5	1 - 3	0.035 - 0.07	8 - 16	5 - 10	0.005 - 0.009	62 - 112	40 - 72
	Unit of Exposure: Baseline (103.8 mg/lb ai)			Unit of Exposure: Additional PPE (3.2 mg/lb ai)			Unit of Exposure: Eng. Controls (mg/lb ai) NONE		
7	2.4	<1	<1	0.073	7	5	None	None	None

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Table 10. Short- and Intermediate-Term Dermal Risk Estimates for Mixer/Loader, Handlers of Azinphos Methyl									
Exposure Scenario	Dose Range (mg/kg/day)	MOE Range		Dose Range (mg/kg/day)	MOE Range		Dose Range (mg/kg/day)	MOE Range	
		short-term	interm-term		short-term	interm-term		short-term	interm-term
	Unit of Exposure: Baseline (3.4 mg/lb ai)			Unit of Exposure: Additional PPE (1.3 mg/lb ai)			Unit of Exposure: Eng. Controls (mg/lb ai) NONE		
8	1.9	<1	<1	0.743	<1	<1	None	None	None
	Unit of Exposure: Baseline (2.5 mg/lb ai)			Unit of Exposure: Additional PPE (1.26 mg/lb ai)			Unit of Exposure: Eng. Controls (mg/lb ai) NONE		
9	0.06	9	6	0.03	19	12	None	None	None
	Unit of Exposure: Baseline (0.01 mg/lb ai)			Unit of Exposure: Additional PPE (0.007 mg/lb ai)			Unit of Exposure: Eng. Controls (0.0002 mg/lb ai)		
10	0.0375	15	9	0.03	19	12	0.0008	700	450

Discussion of Table 10

- The estimates of risk based on dermal exposure in the above table indicate that the MOEs are equal to, or greater than 100 at baseline for short-term or intermediate-term risk for NO scenarios.

- With Additional PPE MOEs are equal to, or greater than 100 for short-term or intermediate-term risk based on dermal exposures for NO scenarios.

- Using Engineering Controls, MOEs for the following scenarios are equal to, or greater than 100:

Short-Term Risk, Based on Short-Term Dermal Exposure

(1c) Mixing/loading liquids for airblast application (all rates analyzed);

(6) Applying sprays with an airblast sprayer (at 1 lb ai/A);

(10) Flagging liquid sprays for aerial application (at 0.75 lb ai/A).

Intermediate-Term Risk

(1c) Mixing/loading liquids for airblast application (at 1.25 lb ai/A); and

(10) Flagging liquid sprays for aerial application (at 0.75 lb ai/A).

- The calculations of risk indicate that the MOEs are not equal to, or greater than 100 despite maximum mitigation measures including additional PPE and engineering controls (where appropriate) for all remaining scenarios.

- There were no data for:

  (3) Baseline and additional PPE for liquids aerial application with a fixed-wing aircraft; and

  (4) Baseline and additional PPE for liquids aerial application with a helicopter.

Table 11 below provides inhalation risk estimates for the 14 major exposure scenarios for any time period of exposure.

Table 11. Inhalation Risk Estimates (Any Time Period) for Mixer/Loader, Handlers of Azinphos Methyl

Exposure Scenario	Dose Range (mg/kg/day)	MOE Range	Dose Range (mg/kg/day)	MOE Range	Dose Range (mg/kg/day)	MOE Range
	Unit of Exposure: Baseline (1.2 μg/ lb ai)		Unit of Exposure: Additional PPE (0.24 μg/lb ai)		Unit of Exposure: Eng. Controls (0.08 μg/lb ai)	
1(a)	0.0045 - 0.009	36 - 71	0.0009 - 0.0018	178 - 356	0.0003 - 0.0006	533 - 1067
1(b)	0.001	320	0.0002 - 0.0003	1600 - 1067	0.00007- 0.00009	3556 - 4571
1(c)	0.0003 - 0.0007	457 - 1067	0.0024 - 0.0096	2286 - 4571	0.00002- 0.00005	6400 - 16000
	Unit of Exposure: Baseline (43.4 μg/lb ai)		Unit of Exposure: Additional PPE (8.68 μg/lb ai)		Unit of Exposure: Eng. Controls (0.24 μg/lb ai)	
2(a)	0.109 - 0.326	1 - 3	0.02 - 0.065	5 - 16	0.0006 - 0.0018	178 - 533
2(b)	0.037 - 0.047	7 - 9	0.007 - 0.009	35 - 46	0.0002 - 0.0003	1067 - 1600
2(c)	0.012 - 0.025	13 - 27	0.0025 - 0.005	64 - 128	0.00007- 0.00014	2286 - 4571
	Unit of Exposure: Baseline (μg/lb ai)		Unit of Exposure: Additional PPE (μg/lb ai)		Unit of Exposure: Eng. Controls (0.068 μg/lb ai)	

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Table 11. Inhalation Risk Estimates (Any Time Period) for Mixer/Loader, Handlers of Azinphos Methyl						
Exposure Scenario	**Dose Range (mg/kg/day)**	**MOE Range**	**Dose Range (mg/kg/day)**	**MOE Range**	**Dose Range (mg/kg/day)**	**MOE Range**
3	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.0003 - 0.0005	640 - 1067
Exposure Scenario	Unit of Exposure: Baseline (μg/lb ai)		Unit of Exposure: Additional PPE (μg/lb ai)		Unit of Exposure: Eng. Controls (0.0018 μg/lb ai)	
4	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	7 x 10^{-6}- 1.4 x 10^{-5}	22K - 45K
	Unit of Exposure: Baseline (0.7 μg/lb ai)		Unit of Exposure: Additional PPE (0.14 μg/lb ai)		Unit of Exposure: Eng. Controls (μg/lb ai) NA	
5	0.0006 - 0.0007	457 - 533	0.0001 - 0.00015	2133 - 3200	NA	NA
	Unit of Exposure: Baseline (4.5 μg/lb ai)		Unit of Exposure: Additional PPE (0.9 μg/lb ai)		Unit of Exposure: Eng. Controls (0.4 μg/lb ai)	
6	0.0013 - 0.0025	128 - 246	0.00025- 0.0005	640 - 1280	0.0001 - 0.0002	1600 - 3200
	Unit of Exposure: Baseline (31.2 μg/lb ai)		Unit of Exposure: Additional PPE (μg/lb ai) NA		Unit of Exposure: Eng. Controls (μg/lb ai) NA	
7	0.0007	457	NA	NA	NA	NA
	Unit of Exposure: Baseline (117 μg/lb ai)		Unit of Exposure: Additional PPE (23.4 μg/lb ai)		Unit of Exposure: Eng. Controls (μg/lb ai) NONE	
8	0.067	5	0.013	25	None	None
	Unit of Exposure: Baseline (30.2 μg/lb ai)		Unit of Exposure: Additional PPE (μg/lb ai) NA		Unit of Exposure: Eng. Controls (μg/lb ai) NA	
9	0.0007	457	NA	NA	NA	NA
	Unit of Exposure: Baseline (0.28 μg/lb ai)		Unit of Exposure: Additional PPE (0.056 μg/lb ai)		Unit of Exposure: Eng. Controls (μg/lb ai) NA	
10	0.001	320	0.0002	1600	NA	NA

Discussion of Table 11

- The estimates of risk based on inhalation exposures in the above table indicate that the MOEs are equal to, or greater than 100 at baseline for risk (any time

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Discussion of Table 11

- The estimates of risk based on inhalation exposures in the above table indicate that the MOEs are equal to, or greater than 100 at baseline for risk (any time period) for the following scenarios:

  (1b) Mixing/loading liquids for groundboom application (at 0.75 to 1.5 lb ai/A);

  (1c) Mixing/loading liquids for airblast application (at 1.0 to 2.0 lb ai/A);

  (5) Applying liquids with a groundboom sprayer (at 0.75 to 1.5 lb ai/A);

  (6) Applying liquids sprays with an airblast sprayer (at 1.0 lb ai/A);

  (7) Mixing/loading/applying liquids with a low pressure handwand (at 0.04 lb ai/gal);

  (9) Mixing/loading/applying liquids with a backpack sprayer (at 0.04 lb ai/gal); and,

  (10) Flagging liquid aerial applications (at 0.75 lb ai/A).

- With Additional PPE MOEs for the following additional scenarios are equal to, or greater than 100 with for risk from inhalation exposures (any time period):

  (1a) Mixing/loading liquids for aerial/chemigation application (at 0.75 lb ai/A);

  (2c) Mixing/loading wettable powders for airblast sprayer application (at 1.0 lb ai/A);

  (5) Applying sprays using a groundboom sprayer (potatoes treated with 0.375 - 0.75 lb ai/A over 80 acres, and tomatoes treated with 0.375 - 1.5 lb ai/A over 50 acres);

  (6) Applying liquid sprays with an airblast sprayer (at 1.0 and 2.0 lb ai/A); and

  (10) Flagging during aerial application, sprays (cotton treated with 0.13 to 0.75 lb ai/A over 350 acres).

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- Using Engineering Controls MOEs for the following additional scenarios are equal to, or greater than 100 risk from inhalation exposures(any time period):

  (2a) Mixing/loading wettable powders for aerial/chemigation application (at 0.5 lb ai/A);

  (2b) Mixing/loading wettable powders for groundboom application (at 0.75 and 1.5 lb ai/A);

  (2c) Mixing/loading wettable powders for airblast sprayer application (at 1.5 to 2.0 lb ai/A);

  (3) Applying liquids with a fixed-wing aircraft (at 0.5 and 4.0 lb ai/A); and

  (4) applying liquids with a helicopter (at all rates).

- Despite maximum mitigation measures including additional PPE and engineering controls (where appropriate) MOEs for the following scenarios are not more than 100:

  (8) Mixing/loading/applying liquids with a high pressure handwand (1000 gal/day).

- There were no data for the following scenarios:

  (3) Baseline and additional PPE data for liquids aerial application with a fixed-wing aircraft. There are engineering controls data for this scenario.

  (4) Baseline and additional PPE data for liquids aerial application with a helicopter. There are engineering controls for this scenario.

ii. Risk from Adding Dermal and Inhalation Exposure. Because the same toxicity endpoint (i.e., RBC cholinesterase inhibition) is applicable to both inhalation and dermal risks, it is appropriate to add these risks together to obtain a total risk for occupational exposure. As seen under i. above, the only scenarios that have MOEs >100 at all label application use rates are (1c) for short-term exposures only and (10)at both short- and intermediate-term exposures. Note that because we consider risks at both short- and intermediate-term exposures at all application rates, scenario 1(c), does not meet the target MOE (100) under all of these conditions. Since all other dermal exposure scenarios result in MOEs <100, aggregating dermal and inhalation risks for these scenarios will also result in MOEs <100.

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In summary, only one exposure scenario at all application rates for both short- and intermediate-term exposures has an MOE >100, scenario (10) for flaggers. Note however, that this scenario has been prohibited along with scenario (9) for backpack sprayers on the currently approved labels. Once these 2 exposure scenarios are deleted, none of the remaining 12 exposure scenarios (both short- and intermediate-term) have MOEs 100 at all application rates for combined dermal and inhalation exposures.

The formula used to combine the dermal and inhalation risks is:

$$CombinedRisk = \frac{1}{\frac{1}{MOE_{dermal}} + \frac{1}{MOE_{inhalation}}}$$

Using this formula, the combined dermal and inhalation risks were calculated for exposure scenarios for which maximum PPE and/or engineering controls were available to control both dermal and inhalation exposures. Risk estimates are given in the Table 12 below. In all cases, combining the inhalation and dermal risk estimates resulted in MOEs that are approximately equal to the dermal risk estimates. This is because the dermal exposures are usually at least one order of magnitude greater than the inhalation exposures.

Table 12. Combined Dermal and Inhalation Risks Estimates (MOEs) for Occupational Scenarios with Additional PPE and/or Engineering Controls

Exposure Scenario	Short-Term Risk Estimates (MOEs)	Intermediate-Term Risk Estimates (MOEs)
1(a)	8 - 85	5 - 57
1(b)	55 -69	35 - 45
1(c)	111 - 221	72 - 139
2(a)	3 - 11	2 - 7
2(b)	27	18
2(c)	55 - 91	35 - 60
3	15 - 27	9 - 18
4	35 - 70	23 - 45
5	80 - 90	51 - 59
6	60 - 108	39 - 70
7	7	5

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Table 12. Combined Dermal and Inhalation Risks Estimates (MOEs) for Occupational Scenarios with Additional PPE and/or Engineering Controls		
Exposure Scenario	**Short-Term Risk Estimates (MOEs)**	**Intermediate-Term Risk Estimates (MOEs)**
8	<1	<1
9	19	12
10	486	351

d. Post-Application Exposures and Risks

Azinphos methyl is widely used on many crops, i.e., apples, cotton, almonds, pears, peaches, walnuts and cherries. Dislodgeable foliar residue (DFR) studies have been submitted to the EPA for use in determining worker risk from post-application activities involved with tomatoes, potatoes, apples, grapes and cotton. None of the studies met all the requirements of Subdivision K. However, despite mostly quality assurance problems with these studies, HED determined that portions of this data set could be used to create the post-application exposure assessments. The raw DFR data were developed into a graphs which display the Best Fit DFR for each formulation (Guthion 2S, Guthion WP50 and Guthion 2L) and each crop (tomatoes, potatoes, apples, grapes and cotton). HED has decided to primarily use data for which the R value is above 0.75. The R value measure closeness of the relationship between the independent and dependent variables. Below are brief descriptions of the DFR studies, the risk estimates and restricted entry intervals (REIs) based on the studies findings, and lists of the other relevant crops for which specific risk estimates could be applied.

A chemical-specific study, "Review of Guthion Foliar Dislodgeable Residue Study" (MRID 408998-01) was used to develop post-application risk for the following sections (tomatoes through grapes). Additional, more recently conducted studies on apples and cotton have been submitted by the registrant. These studies follow more closely the requirements of Subdivision K. They are described later, and used to assess post-application risks with these crops.

i. Post-Application Risk for Tomatoes. In the first tomato study, azinphos methyl, formulated as *Guthion 2S*, was applied 4 times to tomatoes at 8 to 10 day intervals at a rate of 24 oz ai/A (ie., 1.5 lb ai/A) using a backpack sprayer. DFR residues were measured on 0, 1, 2, 5, 7, 14, 21, 28, and 35 DAT. The residues for the leaf samples collected were "single-sided" leaves. Table 13 below outlines the best fit DFR and associated risk. A transfer coefficient of 750 cm^2/hr was assumed for tomatoes (equivalent to 1500 cm^2/hr of a "double-sided" leaf).

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Table 13. Reentry Calculations for Tomatoes Treated with Guthion 2s at 1.5 lb ai/A					
Days After Treatment	**Best Fit DFR (g/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.18	750	1.08	0.015	37
2 (Current REI)	0.1376	750	0.8256	0.01179	48
7	0.0702	750	0.4212	0.0060	93
8	0.0613	750	0.3678	0.0053	106

[1]Best Fit DFR (μg/cm2) = foliar dislodgeable residues.

[2]Transfer Coefficient (cm2/hr) assumed 750 for high exposure crops such as tomatoes.

[3]Exposure (mg/day) = [Best Fit DFR x Transfer Coefficient / 1000 (μg/mg conversion)] x 8 hours/day

[4]Dose (mg/kg/day) = Exposure (mg/day) / BW (70 kg)

[5]MOE = NOAEL (0.56 mg/kg/day) / Daily Dose (mg/kg/day)

In a second tomato study, azinphos methyl, formulated as *Guthion WP50*, was applied 4 times to tomatoes at 8 to 10 day intervals at a rate of 24 oz ai/A (ie., 1.5 lb ai/A) using a backpack sprayer. DFR residues were measured on 0, 1, 2, 5, 7, 14, 21, 28, and 35 DAT. The residues for the leaf samples collected were "single sided" leaves. Table 14 below outlines the best fit DFR and associated risk. A transfer coefficient of 750 cm^2/hr was assumed for tomatoes (equivalent to 1500 cm^2/hr of a "double-sided" leaf).

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Table 14. Reentry Calculations for Tomatoes Treated with Guthion 50WP at 1.5 lb ai/A					
Days After Treatment	**Best Fit DFR (g/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.066	750	0.396	0.0057	98
1	0.062	750	0.372	0.0053	106
2	0.058	750	0.348	0.005	112
7	0.042	750	0.252	0.0036	156

[1]Best Fit DFR (μg/cm2) = foliar dislodgeable residues.

[2]Transfer Coefficient (cm2/hr) assumed 750 for high exposure crops such as tomatoes.

[3]Exposure (mg/day) = [Best Fit DFR x Transfer Coefficient /1000 (μg/mg conversion)] x 8 hours/day

[4]Dose (mg/kg/day) = Exposure (mg/day) / BW (70 kg)

[5]MOE = NOAEL (0.56 mg/kg/day) / Daily Dose (mg/kg/day)

Discussion and Conclusions. Short-term MOEs are 100 for this maximum application rate and crop on day 8 post-application for the 2S product and on day 1 post-application for the 50WP product. This means that for the 50WP, the current REI of 2 days post-application for tomatoes is appropriate for other potentially necessary maintenance activities (eg., hoeing, scouting, thinning, staking).

ii. Post-Application Risk for Potatoes. In the first potato study, azinphos methyl, formulated as *Guthion 2S*, was applied 3 times to potatoes at 14 day intervals at a rate of 24 oz ai/A (ie., 1.5 lb ai/A) using a groundboom sprayer. DFR residues were measured on 0, 1, 2, 7, 21, 28, and 35 DAT. The residues for the leaf samples collected were "single sided" leaf. Table 15 below outlines the best fit DFR and associated risk. A transfer coefficient of 250 cm^2/hr was assumed for potatoes (equivalent to 500 cm^2/hr of a "doubles sided" leaf.

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Table 15. Reentry Calculations for Potatoes Treated with Guthion 2S at 1.5 lb ai/A					
Days After Treatment	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	1.06	250	2.12	0.030	19
2	0.810	250	1.62	0.023	24
3	0.7088	250	1.42	0.020	28
4	0.621	250	1.02	0.015	37
13	0.187	250	0.37	0.005	112

Table 16. Reentry Calculations for Potatoes Treated with Guthion 2S at 1.5 lb ai/A (with DFR values prorated to 0.75 lb ai/A)					
Days After Treatment	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.53	250	1.06	0.015	37
2	0.405	250	0.81	0.012	47
3	0.354	250	0.71	0.010	56
4	0.311	250	0.51	0.0075	75
8	0.182	250	0.36	0.005	112

[1] Best Fit DFR (μg/cm2) = foliar dislodgeable residues.

[2] Transfer Coefficient (cm2/hr) assumed 250 for low exposure crops such as potatoes.

[3] Exposure (mg/day) = [Best Fit DFR x Transfer Coefficient / 1000 (μg/mg conversion] x 8 hours/day

[4] Dose (mg/kg/day) = Exposure (mg/day) / BW (70 kg)

[5] MOE = NOAEL (0.56 mg/kg/day) / Daily Dose (mg/kg/day)

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Discussion and Conclusions. Short-term MOEs are <100 until day 13 post-application under the use conditions of the study. The actual maximum use rate is only 0.75 lb ai/A, and when the DFR values are prorated to this level, the MOE is >100 at day 8. This means that the current REI of 2 days is too short.

In a second potato study, azinphos methyl, formulated as *Guthion WP50*, was applied 3 times to potatoes at 14 day intervals at a rate of 24 oz ai/A (ie., 1.5 lb ai/A) using a groundboom sprayer. DFR residues were measured on 0, 1, 2, 7, 21, 28, and 35 DAT. The residues for the leaf samples collected were "single sided" leaves. Table 17 below outlines the best fit DFR and associated risk. A transfer coefficient of 250 cm^2/hr was assumed for potatoes (equivalent to 500 cm^2/hr of a "double sided" leaf).

Table 17. Reentry Calculations for PotatoesTreated with Guthion WP50 at 1.5 lb ai/A

Days After Treatment	Best Fit DFR ($\mu g/cm^2$)[1]	Tc (cm^2/hr)[2]	Exposure (mg/day)[3]	Dose (mg/kg/day)[4]	Short-Term MOE[5]
0	1.97	250	7.92	0.11	5
10	0.85	250	1.7	0.024	23
12	0.72	250	1.44	0.021	27
13	0.66	250	1.32	0.019	29
28	0.189	250	0.38	0.005	112

Table 18. Reentry Calculations for Potatoes Treated with Guthion WP50 at 1.5 lb ai/A (with DFR values prorated to 0.75 lb ai/A)

Days After Treatment	Best Fit DFR ($\mu g/cm^2$)[1]	Tc (cm^2/hr)[2]	Exposure (mg/day)[3]	Dose (mg/kg/day)[4]	Short-Term MOE[5]
0	0.985	250	1.97	0.028	20
2	0.831	250	1.66	0.024	23
3	0.765	250	1.53	0.022	26
4	0.703	250	1.41	0.020	28

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Table 18. Reentry Calculations for Potatoes Treated with Guthion WP50 at 1.5 lb ai/A (with DFR values prorated to 0.75 lb ai/A)					
Days After Treatment	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
10	0.425	250	0.85	0.012	47
12	0.36	250	0.72	0.010	56
13	0.33	250	0.66	0.009	62
20	0.185	250	0.37	0.005	112

Table 19. Reentry calculations for potatoes treated with Guthion WP50 at 1.5 lb ai/A (with DFR values prorated to 0.5 lb ai/A)					
Days After Treatment	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.66	250	1.32	0.019	30
2	0.55	250	1.12	0.016	35
3	0.51	250	1.02	0.015	37
4	0.47	250	0.94	0.013	43
10	0.28	250	0.56	0.008	70
12	0.24	250	0.48	0.007	80
13	0.22	250	0.44	0.006	93
15	0.187	250	0.37	0.005	112

[1]Best Fit DFR (μg/cm2) = foliar dislodgeable residues.

[2]Transfer Coefficient (cm^2/hr) assumed 250 for low exposure crops such as potatoes.

[3]Exposure (mg/day) = [Best Fit DFR x Transfer Coefficient / 1000] x 8 hours/day

[4]Dose (mg/kg/day) = Exposure (mg/day) /BW (70 kg)

[5]MOE = NOAEL (0.56 mg/kg/day) / Daily Dose (mg/kg/day)

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Discussion and Conclusions. In this study, short-term MOEs of 100 were not achieved until day 15 (after prorating the application rate to 0.5 lb ai/A), indicating that the current 2-day REI is too short. The same is also true after prorating the results of the study to the actual maximum use rate (0.75 lb ai/A).

Other Relevant Crops

Other potential azinphos-treated crops for which the above potato studies may be relevant include: broccoli; Brussels sprout; cabbage; cauliflower; celery; cucumbers; eggplants; onions; and parsley.

iii. Post-Application Risk for Orchard and Citrus Crops. Measurements of field worker exposure (transfer factors) while exposed to azinphos methyl treated orchard and citrus crops have been measured by the California Department of Pesticide Regulation (CDPR). The transfer factors developed by the CDPR will be used in this assessment. The transfer factors developed by CDPR were generated using double-sided residues. However, the transfer factors were adjusted to reflect the single-sided DFR measurements collected by the registrant.

To address reentry exposure to deciduous orchard crops treated with azinphos methyl, the Apple DFR data have been used. The DFRs are presented based on a best fit regression analysis of the wettable powder formulation. The apple DFRs were the result of apples trees treated with 4 applications of 1.5 lb ai/A. The DFRs presented in the following tables have been prorated to reflect various application rates ranging from 2 to 0.5 lb ai/A. According to the registrant, 1 lb ai/A is the typical rate for apples. However because the label has higher rates for apples and other orchard crops, and azinphos is acutely toxic, all rates are being considered in this assessment. The use of lower rates for potential risk mitigation if feasible should be considered. However, with a short-term dermal NOAEL of 0.56 mg/kg/day, MOE's for the orchard uses are well below the Agency's recommended 100 for many uses even with the long existing reentry intervals.

Reentry tasks identified for the orchard crops are harvesting, thinning, and propping. Harvester exposure is estimated based a range of restricted-entry intervals. The use of poles to prop-up tree limbs with heavy fruit set is common in stone fruit crops such as plums. These exposures are much lower than those encountered while thinning fruit and harvesting.

Table 20. Reentry Exposure for Deciduous Orchard Crops Treated with 2 lb ai/A

DAT	DFR ($\mu g/cm^2$)	Task	Transfer Factor (cm^2/hr)	Estimated Exposure (mg/kg/day)	Short-Term MOE
2	3.12	propper	90	0.03	19
2	3.12	thinner	1650	0.58	1
7	2.5	harvester	2090	0.6	0.9
14	2.2	harvester	2090	0.52	1
21	1.4	harvester	2090	0.33	2

Table 21. Reentry Exposure for Deciduous Orchard Crops Treated with 1.5 lb ai/A

DAT	DFR ($\mu g/cm^2$)	Task	Transfer Factor (cm^2/hr)	Estimated Exposure (mg/kg/day)	Short-Term MOE
2	2.34	propper	90	0.024	23
2	2.34	thinner	1650	0.44	1.3
7	1.9	harvester	2090	0.45	1.2
14	1.4	harvester	2090	0.33	1.7
21	1.1	harvester	2090	0.25	2.2

Table 22. Reentry Exposure for Deciduous Orchard Crops Treated with 1 lb ai/A

DAT	DFR ($\mu g/cm^2$)	Task	Transfer Factor (cm^2/hr)	Estimated Exposure (mg/kg/day)	Short-Term MOE
2	1.56	propper	90	0.02	28
2	1.56	thinner	1650	0.29	2
7	1.26	harvester	2090	0.30	2

Table 22. Reentry Exposure for Deciduous Orchard Crops Treated with 1 lb ai/A					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
14	0.93	harvester	2090	0.22	2.6
21	0.7	harvester	2090	0.17	3

Table 23. Reentry Exposure for Deciduous Orchard Crops Treated with 0.75 lb ai/A					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	1.17	propper	90	0.01	56
2	1.56	thinner	1650	0.29	2
7	1.26	harvester	2090	0.30	1.9
14	0.93	harvester	2090	0.22	2.6
21	0.53	harvester	2090	0.125	4.5

Table 24. Reentry Exposure for Deciduous Orchards Treated with 0.5 lb ai/A					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	0.77	propper	90	0.008	70
2	0.77	thinner	1650	0.15	3.7
7	0.63	harvester	2090	0.15	3.7
14	0.47	harvester	2090	0.11	5
21	0.35	harvester	2090	0.08	7

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Other Relevant Crops

Other potential azinphos-treated crops for which the above apple studies may be relevant include: almonds; apricots; cherries; crabapples; filberts; peaches; pears; pecans; pistachios; plums; quinces; and walnuts. It should be noted that post-application risk is considered to be negligible for the mechanical harvesting of crops. This may apply to almond and other tree nut harvesting. It should also be noted, however, that activities ancillary to any mechanical harvesting (this may especially include the use of mechanical blowers to move fallen nuts into wind-rows) can present potentially serious post-application exposures.

iv. Post-Application Risk for Citrus Crops. Recent DFR data following azinphos methyl applications to citrus crops are not available. However, in the CDPR Draft Azinphos Methyl Assessment, DFR's were presented based on a study submitted to California by the registrant (Chemagro at the time) that was conducted in 1970. The DFRs are reported as double sided in the CDPR report. Therefore, the corresponding transfer factor, used in the above deciduous orchard crop tables, reflects that change. The REI for citrus is 30 days.

Table25. Reentry Exposure for Citrus Treated with 3.75 lb ai/A (With DFR Values Prorated to 2 lb ai/A)

DAT	DFR ($\mu g/cm^2$)	Task	Transfer Factor (cm^2/hr)	Estimated Exposure (mg/kg/day)	Short-Term MOE
7	0.59	harvester	4180	0.28	2
30	0.32	harvester	4180	0.15	3.7

Other Relevant Crops

Other potential azinphos-treated crops for which the above citrus study may be relevant include: kiwi fruit and pomegranates.

v. Post-Application Risk for Caneberries and Blueberries. To address reentry exposure while harvesting caneberries and blueberries, DFR data following treatment of grapes with 0.25 lb ai/A were used. The data were prorated to reflect the higher rate of 0.5 lb ai/A. Some label rates reach a maximum rate of 0.75 lb ai/A for blueberries, and 1 lb ai/A for caneberries. However, using these atypically higher rates in the calculation will only worsen an already unacceptably low MOE at the 0.5 lb rate.

Table 26. Reentry Exposure for Caneberries and Blueberries Treated with 0.5 lb ai/A					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	6.19	tying, training, topping	900	0.64	0.9
7	5.13	harvesting	900	0.52	1.1

Table 27. Reentry Exposure for Caneberries and Blueberries Treated with 0.25 lb ai/A					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	3.1	tying, training, topping	900	0.32	1.8
7	2.56	harvesting	900	0.26	2.2

Other Relevant Crops

Other potential azinphos-treated crops for which the above caneberries assessment may be relevant include: snap beans; blackberries; boysenberries; loganberries; raspberries; cranberries; gooseberries; melons; blackeyed peas; peppers; soybeans; and strawberries.

vi . Post-Application Risk for Grapes

Table 28. Reentry Exposure for Grapes Treated with 0.5 lb ai/A					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	6.19	cane throwing, leaf pulling, girdling	9000	6.36	0.1
7	5.13	harvesting	9000	5.28	0.1
21	3.01	harvesting	9000	3.1	0.2

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Table 29. Reentry Exposure for Grapes Treated with 0.25 lb ai/A					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	3.09	cane throwing, leaf pulling, girdling	9000	3.18	0.2
7	2.56	harvesting	9000	2.62	0.2
21	1.51	harvesting	9000	1.55	0.4

vii. Post-Application Risk for Apples Based on Study Results from 1995 DCI. The registrant is a member of the Agricultural Reentry Task Force (ARTF) which is developing a generic worker reentry exposure database. The registrant recently submitted dislodgeable foliar residue (DFR) data from a number of studies on apples and cotton. These data were generated in response to the Agricultural Data Call-In issued by the Agency in 1995. Because concurrent monitoring of reentry workers was not conducted, transfer factors from relevant CDPR assessments are used here, as above. The transfer factors used below are based on "double-sided" leaf residues. A brief description of each study, along with tables of study findings and estimated risks appear below.

In a study entitled, "Determination of Dislodgeable Foliar Residue Levels of Azinphos-Methyl and Azinphos-Methyl-Oxon on an Apple Orchard in the Lower Yakima Valley of Washington State," (MRID 446853-01), Guthion 50WP was applied at a rate of one lb ai/A, in four applications at intervals ranging from 21 to 26 days. Data were collected when spray had dried, at 4 and 12 hours, and at 1, 2, 3, 5, 7, 10, 14 and 21 days following application. A regression analysis was performed and estimated daily residue values made for data collected following the fourth application. The results are as follows:

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Table 30. Reentry Exposure for Apples (Deciduous Orchard Crops) Treated with 1 lb ai/A in Washington State (MRID 446853-01)					
DAT	**DFR (µg/cm²)**	**Task**	**Transfer Factor (cm²/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	3.58	propper	180	0.07	8
2	3.58	thinner	3300	1.4	0.4
7	2.78	harvester	4180	1.3	0.4
14	1.96	harvester	4180	0.94	0.6
21	1.38	harvester	4180	0.66	0.9

In a study entitled, "Evaluation of Foliar Dislodgeable Residues of Guthion on Apples," (MRID 446853-03), two test plots, one in California and the other in New York, were each treated by airblast sprayer with four applications of Guthion 50WP at a rate of one lb ai/A per application with 14-day intervals between treatments. Maximum label application rate is 1.5 lb ai/A, with a 7-day interval. Data were collected immediately after the spray had dried (IASD), or at approximately 2 hours, and at 1, 2, 3, 5, 6, 7, 9, 11, 14, 21, 28 and 35 days following application. A regression analysis was performed and estimated daily residue values made for data collected following the fourth application. The results are as follows:

Table 31. Reentry Exposure for Apples (Deciduous Orchard Crops) Treated with 1 lb ai/A in California (MRID 446853-03)					
DAT	**DFR (µg/cm²)**	**Task**	**Transfer Factor (cm²/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	1.58	propper	180	0.03	19
2	1.58	thinner	3300	0.6	0.9
7	1.52	harvester	4180	0.73	0.8
14	1.43	harvester	4180	0.68	0.8
21	1.35	harvester	4180	0.65	0.9

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Table 32. Reentry Exposure for Apples (Deciduous Orchard Crops) Treated with 1 lb ai/A in New York (MRID 446853-03)					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	0.83	propper	180	0.02	28
2	0.83	thinner	3300	0.31	1.8
7	0.51	harvester	4180	0.24	2.3
14	0.26	harvester	4180	0.12	4.7
21	0.13	harvester	4180	0.06	9.3

In a study entitled, "Evaluation of Airborne Dislodgeable Residue Levels of Azinphos methyl and Azinphos methyl-oxon Following Application of Guthion 35 WP to Apples in Hood River, Oregon," (MRID 446949-01), three test plots were each treated by airblast sprayer with four applications of Guthion 35 WP at a rate of one lb ai/A per application on May 14, June 10, July 15 and August 6, 1992. Data were collected immediately after the spray had dried (IASD), at 4 hours, 12 hours, and at 1, 2, 3, 5, 6, 7, 10, 14, and 21 days following application. A regression analysis was performed and estimated daily residue values made for data collected following the fourth application. The results are as follows:

Table 33. Reentry Exposure for Apples (Deciduous Orchard Crops) Treated with 1 lb ai/A in Oregon (MRID 446949-01)					
DAT	**DFR ($\mu g/cm^2$)**	**Task**	**Transfer Factor (cm^2/hr)**	**Estimated Exposure (mg/kg/day)**	**Short-Term MOE**
2	2.72	propper	180	0.06	9.3
2	2.72	thinner	3300	1.03	0.54
7	2.24	harvester	4180	1.07	0.52
14	1.71	harvester	4180	0.82	0.68
21	1.30	harvester	4180	0.62	0.9

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Discussion andConclusions. The above apple studies have been performed in more strict compliance to Subdivision K Guidelines requirements than the study used to assess post-application risk under section iii above, and for this reason, can be considered more reliable. However, when compared to the results of the older study, the most recent studies present a collaborating picture of post-application risk to apple harvesters. For instance, at the less than maximum, one lb ai/A application rate, which is stated by the registrant to be the most typical, all studies resulted in MOEs <100 at day 21 (i.e., MOEs ranging from 0.9 to 9.3). Existing REIs are shown to be too short by these study results.

viii. Post-Application Risk for Cotton

In a study entitled, "Evaluation of Foliar Dislodgeable Residues of Guthion on Cotton," (MRID 446853-02), test plots at three locations (Texas, Georgia and Mississippi) were each treated by groundboom sprayer with three applications of Guthion 2L (emulsifiable concentrate) at a rate of 0.25 lb ai/A per application. Data were collected immediately after the spray had dried (or about 2 hours), and at 1, 2, 3, 4, 5, 7, 10, 14, 21, 28 and 35 days following application. A regression analysis was performed and estimated daily residue values made for data collected following the third application. The results are as follows:

Table 34. Reentry Calculations for Cotton Treated with Guthion 2L at 0.25 lb ai/A in Texas

DAT	Best Fit DFR ($\mu g/cm^2$)[1]	Tc (cm^2/hr)[2]	Exposure (mg/day)[3]	Dose (mg/kg/day)[4]	Short-Term MOE[5]
0	0.13	4000	4.16	0.06	9
1	0.11	4000	3.52	0.05	11
2	0.097	4000	3.10	0.04	14
7	0.043	4000	1.38	0.02	28
14	0.014	4000	0.45	0.006	93
15	0.012	4000	0.38	0.0055	102

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Table 35. Reentry Calculations for Cotton Treated with Guthion 2L at 0.25 lb ai/A in Mississippi					
DAT	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.024	4000	0.768	0.011	51
1	0.021	4000	0.672	0.01	56
2	0.019	4000	0.608	0.009	62
7	0.012	4000	0.384	0.0055	102

Table 36. Reentry Calculations for Cotton Treated with Guthion 2L at 0.25 lb ai/A in Georgia					
DAT	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.009	4000	0.288	0.0041	137

Table 37. Reentry Calculations for Cotton Treated with Guthion 2L at 0.25 lb ai/A in Georgia (prorated to 0.50 lb ai/A)					
DAT	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.018	4000	0.576	0.0082	68
1	0.016	4000	0.512	0.0073	77
2	0.0156	4000	0.499	0.0071	79
5	0.012	4000	0.384	0.0055	102

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Table 38. Reentry Calculations for Cotton Treated with Guthion 2L at 0.25 lb ai/A in Georgia (Prorated to maximum label rate of 0.75 lb ai/A)					
DAT	**Best Fit DFR (μg/cm^2)[1]**	**Tc (cm^2/hr)[2]**	**Exposure (mg/day)[3]**	**Dose (mg/kg/day)[4]**	**Short-Term MOE[5]**
0	0.027	4000	0.864	0.0123	45
1	0.024	4000	0.768	0.011	51
2	0.023	4000	0.736	0.0105	53
5	0.018	4000	0.576	0.008	70
7	0.015	4000	0.480	0.007	80
11	0.012	4000	0.0384	0.0055	102

[1]Best Fit DFR (μg/cm2) = foliar dislodgeable residues.

[2]Transfer Coefficient (cm2/hr) assumed to be 4000 for scouting late season cotton and hand harvesting crops with medium potential for dermal contact.

[3]Exposure (mg/day) = [Best Fit DFR x Transfer Coefficient /1000 (μg/mg conversion)] x 8 hours/day

[4]Dose (mg/kg/day) = Exposure (mg/day) /BW (70 kg)

[5]MOE = NOAEL (0.56 mg/kg/day) / Daily Dose (mg/kg/day)

Discussion and Conclusions. Studies were conducted at three different geographic locations using a 0.25 lb ai/A application rate. The maximum label rate is 0.75 lb ai/A. In the study conducted in Texas, an acceptable MOE of 102 is not reached until day-fifteen post-application. On day-two post-application (the current REI), the MOE is only 14. In the Mississippi study, a MOE of 102 is reached at day-seven, with the MOE at day-one being 56. In the Georgia study, a MOE of 137 is reached on day-zero (i.e., immediately after the spray has dried). However, when the application rate is pro-rated to 0.5 lb ai/A, a MOE of 102 is reached on day-seven, with the day-one MOE being 77. When pro-rated to the potential maximum application rate of 0.75 lb ai/A, a MOE of 102 is not reached until day 11 post-application, and 1 day after application the MOE is 51. The studies show that the existing two-day REI for cotton is too short in all cases, for application rates of 0.5 lb ai/A and above. Even the "typical rate" of 0.25 lb ai/A resulted in MOEs <100 at day-one post-application at two of the three sites tested.

Overall Discussion of Occupational Post-Application Risk

As discussed above, post-application reentry exposure data were submitted to the Agency in the form of dislodgeable foliar residues (tomatoes, potatoes, apples, grapes and cotton). Concurrent monitoring of reentry workers was not conducted. Although these data do not meet all Subdivision K Guideline requirements, they can be used to estimate reentry exposure when viewed in the context of other data available in the literature and data conducted by the California Department of Pesticide Regulation (Formerly the California Department of Food and Agriculture - CDFA). HED determined that the data submitted by the registrant were useable for assessing post-application risks despite certain limitations primarily due to marginal QA/QC data. The data from the various studies are consistent and reveal the slow dissipation rate for which azinphos methyl is known.

ix. Additional Occupational/Residential Exposure Studies

Handler. Despite these limitations, the data reflect similar levels of dislodgeable residues found in other studies and reveal a slow dissipation rate for azinphos methyl. The registrant is a member of the Agricultural Reentry Task Force (ARTF) which is developing a generic worker reentry exposure database. The registrant has conducted and submitted dislodgeable foliar residue (DFR) data on apples and cotton representing approximately 75 percent of the usage. These data were generated in response to the Agricultural Data Call-In issued by the Agency in 1995 and used in this assessment.

x. Occupational Risk Characterization

Summary of Handler Risks

HED has serious concerns regarding occupational exposures and risks for a number of exposure scenarios during application for pesticide handlers. The estimated risks consider baseline protection (long pants and a long-sleeved shirt, no gloves, and an open cab or tractor), additional personal protective equipment (PPE, which includes a double layer of clothing and gloves), and engineering controls (closed application and mixing systems, and water soluble packets). For dermal short-term and intermediate-term exposures using baseline protection, risks expressed as MOEs were >100 for none of the 14 major applicator/handler scenarios. Risks did not improve using additional PPE, with still no MOEs >100 for the 14 major scenarios. Using engineering controls, short-term dermal MOEs were >100 for 3 out of 14 major scenarios for which engineering controls were applicable (engineering controls are applicable to 11 out of 14 scenarios); but, only two of these have MOEs >100 for intermediate-term exposures. This leaves 12 out of 14 occupational exposure scenarios for which MOEs are <100 and exceed HED's level of concern despite maximum mitigation measures.

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For inhalation exposures (any time period) using baseline protection, risks expressed as MOEs were >100 for 9 out of 14 major applicator/handler scenarios. Risks improved using additional PPE with MOEs >100 for 10 out of 14 major scenarios. Using engineering controls, MOEs were >100 for all 9 major scenarios for which engineering controls were applicable. However, this leaves 1 occupational exposure scenario (mixing/loading/applying sprays using high pressure handwands, as in greenhouses) for which the MOE is less than 100 and exceeds HED's level of concern despite maximum mitigation measures.

When inhalation and dermal risks are combined, and short- and intermediate-term exposures considered, 12 out of 14 occupational exposure scenarios produce MOEs <100. The two scenarios for which MOEs are greater than 100 for both short- and intermediate-term exposures are: 1(c) mixing loading liquids for airblast application, and (10) flagging liquid sprays for aerial application.

Summary of Post-Application Risks

In summary, post-applicator risks from the use of azinphos methyl WP50 formulation on tomatoes at the maximum labeled rate (1.5 lb ai/A) result in MOEs >100 at existing 2-day restricted entry intervals (REIs). Post-applicator risks for uses of the 2S formulation of azinphos methyl on potatoes at the actual maximum application rate of 0.75 lb ai/A and at the existing 2-day REI are too short. Uses of the WP50 formulation on potatoes at 0.75 lb ai/A, also result in MOEs <100 at the existing 2-day REI. Based on apple data (using both the WP and emulsifiable concentrate), post-applicator risks for orchard crops were calculated for harvesting, propping, and thinning activities. MOEs calculated for propper activities were <100 for all application rates >1.0 lb ai/A. MOEs were <100 for all harvesting and thinning activities regardless of the application rates and REIs. MOE were <100 for all post-applicator risks for citrus, grape, and berry uses of azinphos methyl at all labeled use rates and existing REIs. Data for cotton revealed MOEs <100 for application rates of 0.50 to 0.75 lb ai/A (maximum rate) at the existing REI of two days.

HED has serious concern for reentry workers and the post-application exposure and risk associated with all uses of azinphos methyl except its use in the WP50 formulation on tomatoes at 1.5 lb ai/A and the 2L formulation on cotton at 0.25 lb ai/A. Risks expressed as MOEs associated with harvesting and tending activities for all other analyzed crops were well below 100.

e. Residential and Other Non-Occupational Exposures and Risks

At this time, products containing azinphos methyl are intended only for agricultural uses. There are no registered residential uses of azinphos methyl. Therefore, no exposure or risk calculations for residential uses are warranted. Azinphos methyl is a restricted use pesticide (RUP).

f. Incident Reports

Azinphos methyl was one of 28 chemicals for which Poison Control Center data were requested. When both Poison Control Center (PCC) and California data were considered, azinphos methyl ranked fifth among the registered pesticides selected on the basis of a high incidence of pesticide poisonings, relatively high toxicity, and high usage. All of the 28 pesticides were either carbamate or organophosphate insecticides. In California it had the third highest ratio (1982-1989) for cases when the pesticide was considered the primary cause of poisoning of field workers per 1,000 applications. Azinphos methyl ranked fifth on percentage of occupational PCC cases requiring hospitalization. In terms of ratio of PCC hospital admitted cases per 1,000 pounds reported in use, azinphos methyl ranked fourth and in terms of exposures and treatment per reported use it ranked fifth.

Detailed descriptions of 134 cases submitted to the California Pesticide Illness Surveillance Program (1982-1990) were reviewed. In 62 of these cases, azinphos methyl was used alone and was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. Azinphos methyl ranked 20th as a cause of systemic poisoning in California and 40th as a cause of hospitalization. One individual was hospitalized in the period 1982 to 1990. A total of 53 persons had systemic illnesses or 85.5% of 62 persons. Where the crop was identified, 85% of the cases were related to tree crop use. Thirty-one of these cases occurred in 1987 including twenty-five systemic illnesses from non-occupational miscellaneous exposure due to azinphos methyl being applied to an orchard that drifted nearby to residential areas. A summary of the types of illnesses reported are given in table below. Most of the cases described below are reentry violations or spray drift violations. The type of spray equipment and personal protective equipment (PPE) used were not reported frequently enough to determine whether that was a factor in the incidences or not.

Table 39. Cases Due to Azinphos methyl Exposure in California Reported by Type of Illness and Year, 1982-1994

Year	Illness Type					
	Systemic[1]	Eye	Skin	Respiratory	Combined	Total
1982	4	-	-	-	-	4
1983	4	-	-	-	-	4
1984	3	2	-	-	-	5
1985	6	-	-	-	-	6
1986	-	1	-	-	-	1
1987	31	-	1	-	-	32
1988	3	-	-	-	-	3

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Table 39. Cases Due to Azinphos methyl Exposure in California Reported by Type of Illness and Year, 1982-1994						
Year	**Illness Type**					
	Systemic[1]	**Eye**	**Skin**	**Respiratory**	**Combined**	**Total**
1989	1	-	1	-	2	4
1990	1	-	-	-	2	3
1991	3	-	1	-	-	4
1992	1	-	-	-	-	1
1993	2	-	-	-	-	2
1994	1	-	-	-	-	1
Total	**61**	**3**	**3**	**0**	**4**	**70**

[1]Category includes cases where skin, eye, or respiratory effects were also reported.
[2]Category includes eye/skin or eye/respiratory illnesses.

California reported 8 cases of systemic poisoning due to azinphos methyl from 1990 through 1994 and three cases of a skin, one of respiratory effects. Four of the eight cases involved applicators. Cholinesterase tests were available for only one of these cases and was in the normal range. All four cases were considered "possible" in terms of azinphos methyl causing the reported symptoms. Four cases involved exposure to residues in a recently treated field. Two workers thinning peaches were exposed from reentering one day prior to the expiration of the reentry interval. An irrigator and a man operating a mower were also exposed apparently prior to expiration of the reentry interval. In the remaining case a traffic officer responding to a chemical spill was exposed to azinphos methyl and developed symptoms of headache and salivation. Direct over spray of azinphos methyl on a residential population resulted in 40 cases of mild to moderate poisoning symptoms. California reported four cases involving reentry into a treated field, though apparently each case involved a violation of reentry time restrictions.

In summary, an earlier review of azinphos methyl incident data (for the period 1982-1990) concluded it was a significant problem, especially for field worker poisoning. Many of the reported cases have involved violation of the reentry interval or exposure to spray drift. The most recent seven years of data (1988 - 1994) from California have shown a significant drop from the earlier 1982 - 1990 data. It is not clear how much of this decline is due to safer work practices and how much is due to a 1990 California requirement which calls for all applications of azinphos methyl to be reported. This latter reporting requirement might result in a decreased

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poisoning/application ratio. Similar drops in poisoning/application ratios for related pesticides suggest that reporting of usage for other pesticides did increase, and may be responsible for reduced incidences.

Among 28 organophosphate and carbamate pesticides, azinphos methyl was on the borderline between the top five and the other 22 in terms of various measures used to rank the hazard. Measures to reduce spray drift and enforce reentry standards are recommended to prevent poisoning from this pesticide. Other measures to reduce applicator exposure and exposure in other handlers (e.g. closed mixing/loading systems) should be considered and made consistent with requirements for the other organophosphate and carbamate insecticides that are often used as alternatives or substitutes for azinphos methyl and for each other.

Since the review of azinphosmethyl incident reports dated August 21, 1997, some additional pertinent information on Poison Control Center exposures and cholinesterase monitoring data has been found. The earlier review reported 39 occupational and 76 non-occupational symptomatic cases due to exposure to azinphosmethyl (as a single exposure rather than exposure to multiple products) between 1985 and 1992. An additional four years of data covering 1993-1996 found another 14 occupational and 49 non-occupational symptomatic cases due to azinphosmethyl. Overall there does not appear to be any trend from the earlier years to the 1993-1996 time period, though a decline in occupational cases and an increase in non-occupational cases is suggested. However, trends in Poison Control Center data can be affected by the changes in participation by individual centers over the years. Typically, non-occupational exposures occur when bystanders are exposed to field residue or spray drift.

Additional information has been obtained concerning exposures to azinphosmethyl that included measurements of blood cholinesterase levels. This information is summarized below.

California accessed medical monitoring records for 542 agricultural pesticide applicators under medical supervision in 1985 for exposure to the more toxic cholinesterase-inhibiting organophosphate and carbamate pesticides (Ames et al. 1987, 1989). In California, cholinesterase monitoring is required for all pesticide applicators who handle Toxicity Category I or II organophosphate or carbamate pesticides for 30 hours of more in any 30 day period. To be included in the survey, the worker had to have at least one pre-exposure (baseline) cholinesterase measurement and at least one exposure value (mid-season). A data-call-in was issued by the California Department of Food and Agriculture and local Agricultural Commissioners through pesticide application firms to their medical supervisors. Follow up letters were sent and phone calls made to employers, physicians, and laboratories performing tests, but significant under reporting is likely to have occurred. Therefore, these workers may not be representative of all workers undergoing medical monitoring in California. However, they do represent exposure effects verified by medical laboratories. Cholinesterase activity depression of 20 percent or more below baseline was observed in 127 or 23 percent of the 542 workers. Depression of 20 percent or more below baseline represents strong evidence of exposure (Gallo and Lawryk 1991).

Specific pesticide exposure was available for 94 of the 127 cases, based on usage records for the previous two weeks. Of these, 31 percent had been exposed to mevinphos, 21 percent to methomyl, and 21 percent to parathion, the three leading pesticides responsible for cholinesterase inhibition. Of the 94 cases with inhibition, 11% had exposure in the past two weeks to azinphosmethyl. Note that many of the workers were exposed to two or more pesticides during the two weeks before they had cholinesterase depression of 20% or more. Twelve of the workers in this study were reported to have pesticide-related illnesses by their physicians. These data demonstrate that agricultural workers, who mix, load and apply the more toxic pesticides are subject to significant levels of exposure despite the considerable restrictions in place to prevent exposure.

California has maintained a Pesticide Illness Surveillance Program with consistent data collection procedures since 1982 (Data tabulations provide by Louise Mehler,M.D., California EPA). From 1982 through 1996 there were 63 illnesses (with a possible, probable or definite relationship) that included taking a cholinesterase value and exposure azinphosmethyl. In 12 of these cases, azinphosmethyl was considered the primary pesticide responsible for poisoning. Of the 63 cases with some exposure to azinphosmethyl, 22 (35%) had below normal levels of cholinesterase or evidence of a marked increase in cholinesterase (20% or more) subsequent to their exposure. Of the 12 cases where azinphosmethyl was determined to be the primary cause of poisoning, five (42%) had evidence of cholinesterase depression. The evidence consisted of cholinesterase depression below laboratory normal values in three of the five cases and subsequent increases in cholinesterase of 40% or more reported in two of the five.

A study of 20 California peach harvest workers was conducted to test different biomarkers of exposure (McCurdy et al. 1994). Cholinesterase measurements were taken 6 days prior to exposure, on the third day of exposure, and 44 days after initial exposure. Thirty days prior to exposure, azinphosmethyl had been applied to study orchards at a rate of 1.5 lb ai/A. The re-entry period for azinphosmethyl in California is 14 days. In comparison with baseline median values, red blood cell cholinesterase values decreased 7% after 3 days of exposure and 19% over the 6-week harvesting season. The higher reduction in cholinesterase at the end of the study rather than on day 3 of exposure was unexpected and thought to be due to an improper handling of samples collected on day 3. This study did not examine health outcomes in the workers.

A similar study of peach harvesters in California was reported by Schneider et al. 1994. In this study 23 harvesters (exposed) and 10 sorters (considered to have minimal exposure) had baseline cholinesterase levels taken and then entered an orchard 51 days after an application of 1.5 lb ai/A of azinphosmethyl. The reduction in plasma cholinesterase was not significant when harvesters were compared to sorters. However, red blood cell cholinesterase values for harvesters were significantly below those of sorters for two post-exposure blood draws as measured by three testing methods. Compared to their baseline levels exposed harvesters experienced a 10-20% decline in red blood cell cholinesterase. No symptoms of organophosphate poisoning were reported by any of the workers.

Two studies reported in the late 1970s also examined field workers exposed to azinphosmethyl in California. In a study reported by Kraus et al. (1977) 21 peach thinners were monitored who entered the orchard 12-18 hours after spraying. A 15% decline of whole blood cholinesterase was reported over the five days of the study. There were no clinical signs of organophosphate poisoning. Richards et al. (1978) reported on a similar study of peach thinners. In this study eight workers were exposed thinning peaches in a field treated with azinphosmethyl and experienced a 8% decline in red blood cell cholinesterase. No workers reported signs of organophosphate poisoning.

Conclusion. Field workers exposed to residues of azinphosmethyl may experience significant declines in red blood cell cholinesterase. In the monitoring studies examined for this review none of the workers reported ill effects that could be directly attributed to cholinesterase inhibition. Poison Control Centers continue to report symptomatic cases due to azinphosmethyl at a rate of about 16 cases per year.

5. Food Quality Protection Act Considerations

a. Cumulative Risk

Azinphos methyl is a member of the organophosphate class of pesticides. All pesticides of this class contain phosphorus and other members of this class of pesticide are numerous and include phorate, disulfoton, dichlorvos, monocrotophos, dimethoate, dicrotophos, oxydemeton methyl, and methamidophos, to name a few.

In considering whether to establish or reassess tolerances, EPA is required to consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Azinphos methyl is an organophosphate pesticide. EPA considers organophosphates to express toxicity through a common biochemical interaction with cholinesterase which may lead to a myriad of cholinergic effects and, consequently the organophosphate pesticides should be considered as a group when performing cumulative risk assessments. EPA is currently developing methods to conduct cumulative assessments. When these methods are completed and peer reviewed, EPA will proceed with a cumulative assessment of the organophosphates. The current assessments address only the risks posed by azinphos methyl.

b. Aggregate Risk

i. Acute Aggregate Risk. The acute aggregate risk assessment for azinphos methyl will include risks associated with dietary exposure through food and water, only. Because exposure to azinphos methyl from food sources alone exceed HED's level of concern for acute dietary risk, any additional exposure through drinking water would lead to risk estimates that further exceed HED's level of concern. HED defers a calculation of aggregate risk as a result of exposures to azinphos methyl in food and water until exposures through food alone have been reduced to an

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acceptable level. At that time, the OPP can reconsider the extent of the contribution, if any, of azinphos methyl residues in drinking water to the acute exposure and aggregate risk.

ii. Chronic Aggregate Risk. The chronic aggregate risk assessment for azinphos methyl will include risks associated with dietary exposure through food and water, only, because azinphos methyl has no registered residential uses, and therefore, HED has minimal concern regarding residential exposures to azinphos methyl. Anticipated residues and percent crop-treated data for commodities with published tolerances result in an exposure to azinphos methyl through food which represents 13% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (<1 year old) occupies 54% of the RfD and Children (1-6 years old) occupies 33% of the RfD. Conservative model estimates of the average concentration of azinphos methyl in ground water indicate that exposure through drinking water will be minimal. The estimated average concentration in ground water (0.44 ppb) does not exceed drinking water levels of comparison (DWLOCs) for the general U.S. population, females (13+), children (1-6 years old), and infants, non-nursing (<1 year old), 45, 39, 10, and 7 ppb, respectively. The estimated average concentration in ground water is much lower than the calculated DWLOCs for chronic exposure and risk assessments. Reported concentrations of azinphos methyl in ground water specific to areas with karst terrain should be verified with additional monitoring. Estimated concentrations of azinphos methyl in surface waters range from a low of 0.08 to 13.4 ppb depending on which model scenario is chosen.

Based on the concentration estimates of azinphos methyl in ground and surface water used in this analysis, the chronic exposure from azinphos methyl in the diet and in drinking water from registered uses of azinphos methyl, is not of concern. Based on the upper-bound concentration estimates of azinphos methyl in surface water (13.4 ppb) from a worst-case cotton-use-scenario using maximum label rates, there may be a potential concern for the children and infants subgroup. However, all other concentration estimates of azinphos methyl in surface water from all other use scenarios modeled indicate that chronic exposure from azinphos methyl in drinking water from registered uses of azinphos methyl, is not of concern. The registrant has submitted labels with fewer applications resulting in lower use rates on cotton. The drinking water risk assessment can be refined to reflect the lowered rates. It is anticipated that this label change on cotton will mitigate the potential risk estimated based the existing label rates on cotton.

The Agency bases this determination on a comparison of estimated concentrations of azinphos methyl in ground and surface water to back-calculated "levels of comparison" for azinphos methyl in drinking water. These levels of comparison in drinking water were determined after HED has considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in this action. The estimates of azinphos methyl in ground and surface water are derived from a water quality model that uses conservative assumptions (health-protective) regarding the pesticide transport from the point of application to ground water. Because HED considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, HED will reassess the potential impacts of azinphos methyl on drinking water as a part of the aggregate risk assessment process.

c. Endocrine Disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inert) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1996) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

d. Special Sensitivity to Infants and Children

The need for application of a FQPA factor to ensure the protection of infants and children from exposure to azinphos methyl, as required by FQPA, was considered by the FQPA Safety Factor Assessment Review Committee. The Committee determined that the additional safety factor should be removed for azinphos methyl. This decision was based in part on the assessment provided to the committee by the HIARC. The HIARC recommended that the additional 10x factor should be removed because:

- Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposure in rats and rabbits.

- Both a one- and a two-generation reproductive toxicity study in rats showed no increased susceptibility in pups when compared to adults.

- There was no evidence of abnormalities in the development of the fetal nervous system in the pre/postnatal studies. Neither brain weight nor histopathology (nonperfused) of the nervous system was affected in the subchronic and chronic toxicity studies.

- The toxicology database is complete and there are no data gaps. There is no evidence to require a developmental neurotoxicity study.

APPENDIX I

Product Chemistry Data Summary

Case No. 0235
Chemical No. 058001

Case Name: Azinphos methyl
Registrant: Gowan Company
Product(s): 94% T (EPA Reg. No. 10163-95)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number
830.1550	Product Identity and Disclosure of Ingredients	N	
830.1600 830.1620 830.1650	Starting Materials and Manufacturing Process	N	
830.1670	Discussion of Formation of Impurities	N	
830.1700	Preliminary Analysis	N	
830.1750	Certification of Ingredient Limits	N	
830.1800	Analytical Methods to Verify the Certified Limits	N	
830.6302	Color	N	
830.6303	Physical State	N	
830.6304	Odor	N	
830.6313	Stability	N	
830.6314	Oxidation/Reduction	N	
830.6315	Flammability	N	
830.6316	Explodability	N	
830.6317	Storage Stability	N	
830.6319	Miscibility	N	
830.6320	Corrosion Characteristics	N	
830.7000	pH	N	
830.7050	UV/Visible Absorption	N [2]	
830.7100	Viscosity	N	
830.7200	Melting Point/Melting Range	N	
830.7220	Boiling Point/Boiling Range	N	
830.7300	Density/Relative Density/Bulk Density	N	
830.7370	Dissociation Constant in Water	N	

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830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	N	
830.7840 830.7860	Solubility	N	
830.7950	Vapor Pressure	N	

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product Identity and Disclosure of Ingredients	Y	40158701, CSF 2/3/88, CSF 10/31/94
830.1600 830.1620 830.1650	Starting Materials and Manufacturing Process	Y	40158701
830.1670	Discussion of Formation of Impurities	Y	40502301
830.1700	Preliminary Analysis	Y	40502302, **44121302, 44121303**
830.1750	Certification of Ingredient Limits	N [3]	40502302, **44121302, 44121303,** CSF 2/3/88, CSF 10/31/94
830.1800	Analytical Methods to Verify the Certified Limits	Y	40502302, **44121301**
830.6302	Color	Y	40158702
830.6303	Physical State	Y	40158702
830.6304	Odor	Y	40158702
830.6313	Stability	N [4]	40502303
830.6314	Oxidation/Reduction	Y	40200501
830.6315	Flammability	N/A [5]	
830.6316	Explodability	Y	40200501
830.6317	Storage Stability	Y	40502304
830.6319	Miscibility	N/A [5]	
830.6320	Corrosion Characteristics	Y	40200501, 40502303
830.7000	pH	N/A [6]	
830.7050	UV/Visible Absorption	N [7]	
830.7100	Viscosity	N/A [5]	

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830.7200	Melting Point/Melting Range	Y	40158702
830.7220	Boiling Point/Boiling Range	N/A [5]	
830.7300	Density/Relative Density/Bulk Density	Y	40200501
830.7370	Dissociation Constant in Water	N/A [6]	
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	Y	40158702
830.7840 830.7860	Solubility	Y	40158702
830.7950	Vapor Pressure	Y	40158702

[1] Y = Yes; N = No; N/A = Not Applicable. CBRS has determined, based on comparison of the CSFs (dated 2/3/88 for the 85% T and 10/31/94 for the 85% FI), that the composition of the Makhteshim 85% FI is identical to the composition of the Makhteshim 85% T; thus, the 85% FI should be identified as a technical product, and data requirements for the 85% FI will be fulfilled by data submitted for the 85% T.

[2] **Bolded** references were reviewed under CBRS No. 17844, 4/2/97, F. Fort; all other references were reviewed in the Azinphos methyl Reregistration Standard Update dated 1/8/91 for the 85% T, except for the CSF dated 1/31/94 for the 85% FI which was obtained from the product jacket.

[3] A revised certified limits for the active ingredient must be proposed.

[4] Additional data are required concerning the stability of the TGAI upon exposure to metals and metal ions.

[5] Data are not required because the TGAI/MP is a solid at room temperature.

[6] Data are not required because the TGAI/MP is not dispersible in water.

[7] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

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APPENDIX II

TABLE A. FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION FOR Azinphos methyl (CASE 0235).

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Food/Feed Uses					
Alfalfa					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301]	0.5 lb/A	1 (per cutting)	N/A [c]	PHI: 14 days at ≤0.38 lb ai/A; 16 days at 0.5 lb ai/A. Not for use on alfalfa grown for seed. 10 gal/A ground, 1 gal/A aerial
	3 lb/gal FlC [3125-338] [3125-427]	0.75 lb/A	2 (per cutting) at <0.25 lb ai/A	10	PHI: 14 days at ≤0.38 lb ai/A; 21 days at 0.5 lb ai/A; 28 days at >0.5 lb ai/A.
Almonds					
Foliar broadcast Ground and aerial equipment	2 lb/gal EC [3125-426]	2 lb/A	2	30	60-day PHI Do not apply after husks split

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Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
	35% WP [3125-378] [3125-379] 50% WP [3125-301] [3125-193]		2	28	28-day PHI Do not apply within 25 ft of an aquatic site 400 gal/A ground, 20 gal/A aerial

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Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Apples					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] [VT800004]	1.5 lb/A	4	7	7-day PHI Apply up to 6 lb/A/season
	3 lb/gal FlC [3125-338] [3125-427]	0.75 lb ai/A			7-day PHI 3 lb ai/A/season
Artichokes					
Foliar broadcast Ground equipment	2 lb/gal EC [3125-426]	1.5	3	14	30-day PHI
Birdsfoot trefoil (East of the Mississippi River only)					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301]	0.5 lb/A	1 (per cutting)	N/A	PHI: 14 days at ≤0.38 lb ai/A; 16 days at 0.5 lb ai/A. 10 gal/A ground, 1 gal/A aerial

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Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Blackberries, boysenberries, loganberries, raspberries Eastern and North Central U.S. only)					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.5 lb/A	2	NS [c]	14-day PHI Apply aerially in a minimum of 1 gal/A. A 3-day PHI is specified for 2 applications to the lower part of canes at 0.5 lb ai/A.
Blueberries					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.75 lb/A	3	10	7-day PHI

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Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Broccoli					
Drench at planting and foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.75 lb/A	3	NS	15-day PHI
Brussels sprouts					
Drench at planting and foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.75 lb/A	3	NS	7-day PHI

1011148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Cabbage					
Drench at planting and foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.75 lb/A	3	NS	21-day PHI
Cauliflower					
Drench at planting and foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.75 lb/A	3	NS	15-day PHI

102148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Celery					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426] [OH810017]	0.5 lb/A	3	NS	14-day PHI
Cherries					
	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301]	0.75 lb/A	2	14	15-day PHI In CA apply only after harvest Maximum of 3 lb ai/A/season

103448

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
	3 lb/gal FlC [3125-338] [3125-427]	East of Rocky Mts 0.75 lb/A West of Rocky Mts 0.5 lb/A	4 2	14	21-day PHI (east) 7-day PHI (west)

1042148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Citrus fruits					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	2 lb/A	2	NS	7-day PHI for 1 appl 28-day PHI for 2 appl
Cotton					
Foliar broadcast Ground and aerial equipment (conventional or low volume)	2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.5 lb/A	12	NS	0-day PHI for machine harvesting For hand picking, 1-day PHI at ≤0.5 lb/A, 17-day PHI at >0.5 lb/A Maximum seasonal rate 6 lb ai/A for ECs No maximum specified for FlCs
	3 lb/gal FlC [3125-338] [3125-427]	0.5 lb ai/A 0.75 west of Rocky Mts			

1058148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Foliar broadcast Ground and aerial equipment (Ultra low volume)	2 lb/gal EC [3125-102] [3125-123] [3125-426] [CA810074] [MS840012] [TX840005] [TX900011]	0.25			0-day PHI for machine harvesting For hand picking, 2-day PHI Maximum seasonal rate 3 lb ai/A

1062148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Crabapples					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301]	1.5 lb/A	4	7	7-day PHI Apply up to 6 lb/A/season
Cranberries					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-426] [MA780002]	1 lb/A	3	14	A 21-day PHI is specified.
Cucumbers					

1072148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.5 lb/A	3	7	A 1-day PHI is specified.

1084148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Eggplant					
Foliar broadcast Ground equipment	2 lb/gal EC [3125-426]	0.5 lb/A	3	7	A 21-day PHI is specified.
Filberts (pacific northwest only)					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	2 lb/A	3	14	A 45-day PHI is specified on 3125-378, -379, -and -102. A 30-day PHI remains on 3125-193, -301, and -426.
Grapes					

1097/108

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426] [CA800146]	1 lb/A	3	14	0-day PHI for application at 0.75 lb ai/A. 10-day PHI is specified for 1 lb ai/A.

110/148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./cro p [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Melons					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.5 lb/A	3	5	A 7-day PHI is specified.
Nectarines and Peaches					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	1.125 lb/A (Eastern U.S.) 2 (West of the Rocky Mts)	NS	14	A 21-day PHI is specified A total of 3.38 lb ai/A per crop season may be applied.

1112148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Onions (green and dry)					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.75 lb/A	3	7 (bulb) 10 (green)	PHIs of 28 days (dry) and 14 days (green) are specified.
Parsley (root and moss curled)					
Foliar broadcast Ground equipment	50% WP [NJ940002] [NJ940003] [OH810017]	0.5 lb/A	3	NS	A PHI of 21 days is specified
Pears					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301]	1.5 lb/A	4	7	7-day PHI Apply up to 6 lb/A/season

112/148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
	3 lb/gal FlC [3125-338] [3125-427]	0.75 lb/A			7-day PHI Apply up to 3 lb/A/season

1138148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Pecans					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	2 lb/A	3	7	45-day PHI listed on 3125-378, -379, -102 No PHI listed on 3125-193, -301, 426. "Do not apply after shuck-split" specified on 3125-193, -301, -426.
Peppers					
Foliar broadcast Ground equipment	2 lb/gal EC [3125-426]	0.5 lb/A	3	7	A 21-day PHI is specified.
Plums/fresh prunes					

1149148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	1.5 lb/A (Eastern U.S.) 2 lb/A (West of the Rocky Mts)	NS	10	A 15-day PHI is specified. A total of 3.38 lb ai/A may be applied per crop season

1152148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Pistachios					
Foliar broadcast Ground equipment	50% WP [CA790149]	2.5 lb/A	1	N/A	A 21-day PHI is specified. Apply prior to 10% hull split.
Pomegranates					
Foliar broadcast Ground equipment	2 lb/gal EC [CA900021]	1 lb ai/A	2	30	A 55-day PHI is specified.
Potatoes					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426] 3 lb/gal FlC [3125-338] [3125-427]	0.75 lb/A	3	7	A 7-day PHI is specified.
Quinces					

1162148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Foliar broadcast Ground equipment	50% WP [CA900012]	1.5 lb/A	4	7	7-day PHI Apply up to 6 lb/A/season

117148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Rye					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.5 lb/A	1	N/A	A 30-day PHI/PGI is specified.
Strawberries					
Foliar broadcast Ground equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	0.5 lb/A	4	5	A 5-day PHI is specified.

1182148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Sugarcane					
Foliar broadcast Ground and aerial equipment Conventional and ultra low volume sprays	2 lb/gal EC [3125-102] [3125-123] [3125-426] 3 lb/gal FlC [3125-338] [3125-427]	0.75 lb/A	5 (TX, FL) 2 (LA)	21 (LA)	A 30-day PHI is specified. For use in FL, LA, and TX only. In LA, do not apply within 100 ft of lakes, reservoirs, rivers, permanent streams, marshes, ponds, canals, estuaries, or commercial fish farm ponds. 3125-426 and 3425-427 not for use in LA.
Tomatoes					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	1.5 lb/A	4	7	A 0-day PHI is specified for rates ≤0.75 lb ai/A A 14-day PHI is specified for rates >0.75 lb ai/A

192148

Table A. Continued.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No./ SLN No.]	Max. Single Application Rate (ai)	Maximum # of Apples./crop [a]	Minimum Retreatment Interval (Days)	Use Limitations [b]
Walnuts					
Foliar broadcast Ground and aerial equipment	35% WP [3125-378] [3125-379] 50% WP [3125-193] [3125-301] 2 lb/gal EC [3125-102] [3125-123] [3125-426]	2 lb/A	3	14	A 21-day PHI is specified.

a Label-specified maximum number of applications, regardless of rate.

b The following restrictions appear on end-use product labels:

Rotational crops: A 6-month plant-back interval (PBI) is specified for root crops not having azinphos methyl uses, and a 30-day PBI is specified for all other crops not having azinphos methyl uses [all labels].

Restricted entry interval (REI): 24 hours [3125-426 and -427]. 48 hours (72 hours in areas where average rainfall is <25 in/yr) [all other labels]

Pregrazing interval: Do not graze livestock in treated orchards or groves for 21 days after treatment [all labels].

120848

Do not treat greenhouse-grown crops [all labels].

[c] N/A = not applicable; NS = not specified.

APPENDIX III

Table B. Residue Chemistry Science Assessments for Reregistration of Azinphos methyl.

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
860.1200: Directions for Use	N/A	Yes[2]	See Table A.
860.1300: Nature of the Residue			
- Plants	N/A	No	00100826 00107018 00112112 00155026 00155065 **40581701** **40581702** **40581703** **40755801** 43221701[3] 43221702[3] 43221704[3] 43750501[3] GS0235008
- Livestock	N/A	No	00090275 00090278 00155019 00155020 00155021 **40581704** **40581705** 43221703[3] 43834501[4]
860.1340: Residue Analytical Methods	N/A	No	00030303 00080102 00089642 00089740 00090126 00090127 00090274 00090277 00090279 00090946 00093572 00106832 00107018 00107020 00112052 00112054 00112074 00112083 00112093 00112114 00112116 00112120 00112145 00141541 00155064 00158905 00158906 05004211 GS0235014 GS0235015 **41456132** **41456134**
860.1360: Multiresidue Method	N/A	No	

1228148

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
860.1380: Storage Stability	N/A	No	00030303 00090127 00090275 00112078 00155064 43738901[5] 43890001[6]
860.1500: Magnitude of the Residue in Crop Plants			
<u>Root and Tuber Vegetables Group</u>			
- Parsley, root	2 [§180.154(a)]	No	00112073
- Potatoes	0.3 [§180.154(a)]	No	00112039 00112053 40814701[7]
<u>Bulb Vegetables (*Allium spp.*) Group</u>			
- Onions	2 [§180.154(a)]	No	00112111 **41456111 41456112**
<u>Leafy Vegetables (Except Brassica Vegetables) Group</u>			
- Celery	2 [§180.154(a)]	No[8]	00107018
- Parsley	5 [§180.154(a)]	No[8]	00112073
- Spinach	2 [§180.154(a)]	No[9]	00089740
<u>Brassica (Cole) Leafy Vegetables Group</u>			
- Broccoli	2 [§180.154(a)]	No[10]	00080143 00080144 00107020 00112116 00154989 44035402[11]
- Brussels sprouts	2 [§180.154(a)]	No[8]	00090127 00154989
- Cabbage	2 [§180.154(a)]	No[10]	00112116 00107020
- Cauliflower	2 [§180.154(a)]	Yes[10]	00112116 00107020 44035401[12]

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OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
Legume Vegetables (Succulent or Dried) Group			
- Beans, dry	0.3 [§180.154(a)]	No[9]	00087512 00089740 00090946 00107019 00112052 00154989
- Beans, succulent	2.0 [§180.154(a)]	No[9]	00087512 00089740 00090946 00107019 00112052 00154989
- Peas, blackeyed	0.3 [§180.154(a)]	No[9]	00107019 00112035 00112052
- Soybeans	0.2 [§180.154(a)]	No[9]	00107020 00112039 00112052 00112086 00112151
Fruiting Vegetables (Except Cucurbits) Group			
- Eggplant	0.3 [§180.154(a)]	No[8]	
- Peppers	0.3 [§180.154(a)]	No[8]	00107020 **41456114**
- Tomatoes	2.0 [§180.154(a)]	No	00080143 00089740 00112120 00154996 00154989 **41456113**
Cucurbit Vegetables Group			
- Cucumbers	2.0 [§180.154(a)]	No	00107019 **41456110**
- Melons	2.0 [§180.154(a)]	No	00107018 **41456101 41456102 41456103**
Citrus Fruits Group	2.0 [§180.154(a)]	No	00090126 00106832 00112037 00112139 00112143 00112145 **41456104 41456105 41456106 41456130**
Pome Fruits Group			

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OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
- Apples	2.0 [§180.154(a)]	No	00087512 00100824 00112113 00112137 00154989 40224401[13] **41456115**
- Crabapples	2.0 [§180.154(a)]	No[14]	
- Pears	2.0 [§180.154(a)]	No[14]	00087512 00100824 00155064 00154989
- Quinces	2.0 [§180.154(a)]	No[14]	
<u>Stone Fruits Group</u>			
- Apricots	2.0 [§180.154(a)]	No[9]	00100824 00154989 **41456120**
- Cherries	2.0 [§180.154(a)]	No[15]	00107020 00112145 00154989 40679301[16]
- Nectarines	2.0 [§180.154(a)]	No[17]	00154989 **41456117**
- Peaches	2.0 [§180.154(a)]	No	00100824 00154989 **41456121**
- Plums	2.0 [§180.154(a)]	No	00107020 00154989 **41456119**
<u>Berries Group</u>			
- Blackberries, boysenberries, loganberries, raspberries	2.0 [§180.154(a)]	No	0089890 00112142 00112143 42076801[18]
- Blueberries	5.0 [§180.154(a)]	No	00089740 00127018 00112143 **41456118**
- Gooseberries	5.0 [§180.154(a)]	Yes[19]	
<u>Tree Nuts Group</u>			
- Almonds	0.3 [§180.154(a)]	No	00109278 00112159 00158908 40167201[20] **41135501**
- Almond hulls	10.0 [§180.154(a)]		

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OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
- Filberts	0.3 [§180.154(a)]	No[21]	00089740 00112117
- Pecans	0.3 [§180.154(a)]	No	00112126 **41456107**
- Walnuts	0.3 [§180.154(a)]	Yes[22]	00112052 **41456108**
<u>Cereal Grains Group</u>			
- Barley, grain	0.2 [§180.154(a)]	No[9]	00093570 00093572
- Oats, grain	0.2 [§180.154(a)]	No[9]	00093570 00093572
- Rye, grain	0.2 [§180.154(a)]	No	00093572
- Wheat, grain	0.2 [§180.154(a)]	No[9]	00080143 00080144 00093570 00093572 00154989
<u>Forage, Fodder, and Straw of Cereal Grains Group</u>			
- Barley forage and straw	2.0 [§180.154(a)]	No[9]	00093570 00093572
- Oats forage, hay, and straw	2.0 [§180.154(a)]	No[9]	00093570 00093572
- Rye forage, hay, and straw	2.0 [§180.154(a)]	No	00093572
- Wheat forage, hay, and straw	2.0 [§180.154(a)]	No[9]	00080143 00080144 00093570 00093572 00154989
<u>Grass Forage, Fodder, and Hay Group</u>			
- Grasses, forage	2.0 [§180.154(a)]	No[9]	00070492 00112035 00117750
- Grasses, hay	5.0 [§180.154(a)]	No[9]	00070492 00112035 00117750
<u>Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group</u>			

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OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
- Alfalfa, forage	2.0 [§180.154(a)]	No	00035980 00067494 00090273 00090276 00090280 00154989 **41456125**
- Alfalfa, hay	5.0 [§180.154(a)]	No	00035980 00067494 00090273 00090276 00090280 00154989 **41456125**
- Birdsfoot trefoil, forage	2.0 [§180.154(a)]	No[23]	
- Birdsfoot trefoil, hay	5.0 [§180.154(a)]	No[23]	
- Clover, forage	2.0 [§180.154(a)]	No[24]	00090273 00090280 **41456124**
- Clover, hay	5.0 [§180.154(a)]	No[24]	00090273 00090280 **41456124**

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OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
Miscellaneous Commodities			
- Artichokes	2.0 [§180.154(a)]	No[8]	00089740 **41456109**
- Cottonseed	0.5 [§180.154(a)]	Yes[25]	00029078 00045038 00080143 00080144 00087511 00098957 00102272 00122299 00112027 00112039 00112054 00112071 00112110 00112112 00112114 00141541 00154989
- Cranberries	2 [§180.154(a)]	No	00089740 **41456122** 43878001[26]
- Grapes	5 [§180.154(a)]	No	00089642 00112108 00112143 00154989 **41456116**
- Kiwi fruit	10 [§180.154(a)]	No[9]	00112072 00158909
- Pistachios	0.3 [§180.154(a)]	No	00112074
- Pomegranates	0.1 [§180.154(b)]	No	40581701[27] 40755801[27]
- Strawberries	2 [§180.154(a)]	No	00107020 **41456123**
- Sugarcane	0.3 [§180.154(a)]	No	00091562 00112024 00112026 00112083 00112115
- Tobacco	NA	No	
860.1520: Magnitude of the Residues in Processed Food/Feed			
- Apple	None	No[28]	00154989 00100824 **41456127**
- Barley	None	No	

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OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References[1]
- Citrus	5 [§186.2225]	No[29]	00090126 00112037 00112143 **41456130**
- Cottonseed	None	No	00102272 00112039 00112054 00112112 00112071 **41456126**
- Grape	None	No	00089642 00112108 00112143 00154989 **41456129**
- Oats	None	No	
- Plum	None	No	**41456119**
- Potato	None	No	00154989 **41456128** 43957101[30]
- Rye	None	No[31]	
- Soybean (oil)	1 [§185.2225]	No[32]	
- Sugarcane (bagasse)	1.5 [§186.2225]	No[33]	
- Tomato	None	No	**41456131**
- Wheat	None	No	
860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs		No	
- Cattle, goats, horses, sheep: meat, fat, mbyp	0.1 [§180.154(a)]	No[34]	00030303 00090126
- Milk	0.04 **[§180.154a]**	No[34]	00030303 00090126
860.1400: Magnitude of the Residue in water, fish, and irrigated crops	N/A	N/A	
860.1460: Magnitude of the Residue in Food Handling Establishments	N/A	N/A	
860.1850: Confined Accumulation in Rotational Crops	N/A	No	<u>41393601</u>
860.1900: Field Accumulation in Rotational Crops	None	No	<u>00030279</u>

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1. Non-bolded references were cited in the Azinphos methyl Guidance Document dated 9/86. **Bolded** references were reviewed/cited in the Azinphos methyl Reregistration Standard Update dated 1/91. Underlined references were reviewed by EFED, but have not been reviewed by CBRS. Other references were reviewed as noted.

2. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under OPPTS GLN 860.1200: Directions for Use.

3. CBRS Nos. 16463/16388, DP Barcodes D220772/D219719, 12/19/95, S. Knizner.

4. CBRS No. 17510, DP Barcode D229091, 2/9/97, F. Fort.

5. CBRS No. 16383, DP Barcode D220423, 12/12/95, S. Knizner.

6. CBRS No. 16871, DP Barcode D222840, 6/28/96, F. Fort.

7. CBRS No. 4449, 11/30/88, L. Propst.

8. Although the registrant does not intend to support this use (CBRS No. 16871, DP Barcode D222840, 6/28/96, F. Fort), this crop remains on some product label(s). However, IR-4 intends to support this use.

9. There is no registered use on this crop; therefore, the established tolerance should be revoked. However, for the following crops, spinach and succulent beans, IR-4 intends to provide residue data in support of these registrations.

10. IR-4 has submitted adequate field trial data to support to tolerances on broccoli. Additional field trial data are required to support cauliflower use. Additional field trials should be conducted in Regions 1, 5, and 12 for cauliflower. Alternatively, field trial data on cabbage conducted in Regions 1, 2, 3, 5, 6, and 10 may be done if the registrant desires a head and stem Brassica crop subgroup tolerance.

11. CBRS No. 17846, DP Barcode D234678, 3/27/97, F. Fort

12. CBRS No. 17845, DP Barcode D234677, 4/2/97, F. Fort

13. CBRS No. 2552, 9/29/87, W. Anthony.

14. Data on apples support the tolerances on crabapples, pears, and quinces.

15. Data submitted for plums are being used to support the use on cherries.

16. CBRS No. 5592, 9/28/89, K. Dockter.

17. Data from peaches will be used to support nectarines.

18. CBRS No. 9195, DP Barcode D172624, 8/27/92, B. Cropp-Kohlligian.

19. Although the registrant has stated their intent to support the tolerance on gooseberries (CBRS No. 16871, DP Barcode D222840, 6/28/96, F. Fort), there are no registered uses. The

registrant may propose use directions or request deletion of the tolerance. The data submitted for blueberries may be translated to gooseberries.

20. CBRS No. 2215, 8/19/87, W. Anthony.

21. Data on pecans will be used to support filberts.

22. Bayer Corp. intends to submit additional residue data (CBRS No. 16871, DP Barcode D222840, 6/28/96, F. Fort).

23. Data on alfalfa will used to support birdsfoot trefoil.

24. Although the registrant has stated the intent to support the tolerances on clover (CBRS No. 16871, DP Barcode D222840, 6/28/96, F. Fort), there are no registered uses. The registrant may propose use directions or the request deletion of the tolerance. The data submitted for alfalfa may be translated to clover.

25. For purposes of reregistration, additional residue data are required on cotton gin byproducts. Data are required depicting azinphos methyl residues in/on cotton gin byproducts ginned from cotton harvested on the day after the last of multiple foliar applications of azinphos methyl at the maximum labeled rate and totaling 6.0 lb ai/A/season. The cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue from the ginning process. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials.

26. CBRS No. 16870, DP Barcode D222919, 4/18/96, F. Fort.

27. CB No. 4505, no DP Barcode, 4/19/89, M. Nelson.

28. Residues concentrated 2x in wet apple pomace; a feed additive tolerance must be proposed.

29. An adequate processing study on citrus indicated that residues do not concentrate in dried citrus pulp; therefore the established tolerance should be revoked. Residues concentrated 7.5x in citrus oil; a food additive tolerance must be proposed.

30. CBRS No. 17164, DP Barcode D225279, 6/5/96, F. Fort.

31. No processing study exists on rye grain or on any other small cereal grain. However, as residues were <0.01 ppm, one twentieth the tolerance, and the theoretical concentration factor is 10x, a processing study is not required.

32. As there is no registered use on soybeans, the FAT for soybean oil should be revoked.

33. Sugarcane bagasse is not a significant livestock feed item; therefore the FAT for this commodity should be revoked.

34. A 40 CFR §180.6(a)(3) situation exists for azinphos methyl residues in ruminant tissues and milk and the tolerances should be revoked.

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