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Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Oryzalin

Report of the Food Quality Protection Act (FQPA)
Tolerance Reassessment Progress and Risk Management
Decision (TRED) for Oryzalin

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I. Regulatory Determination

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. Existing tolerances associated with oryzalin must be reassessed in accordance with FFDCA, as amended by FQPA. Ecological and occupational assessments were originally conducted at the time of the Oryzalin Reregistration Eligibility Decision (RED) in 1994. Therefore, no further ecological or occupational assessments were conducted as part of this Report of the FQPA Tolerance Reassessment Progress and Risk Management Decision for Oryzalin (also referred to as a TRED).

The Agency has evaluated the human health risks associated with all currently registered uses of oryzalin and has determined that there is a reasonable certainty that no harm will occur to any population subgroup resulting from aggregate exposure to oryzalin. In making this determination, EPA has considered dietary exposure from food and drinking water and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, the fourteen (14) tolerances established for residues of oryzalin in/on raw agricultural commodities are now considered reassessed as safe under section 408(q) of FFDCA, as amended by FQPA.

When EPA completed the Oryzalin RED in 1994, the Agency did not have sufficient information to determine the reregistration eligibility of oryzalin products for use on residential lawns and turf. EPA was unable to estimate post-application or re-entry risks from these uses due to lack of data. Therefore, the Agency required confirmatory exposure monitoring studies for the lawn and turf use as part of the RED. These studies have been conducted by the registrant and evaluated by the Agency. With this new information, EPA is now able to estimate exposure and risks from the lawn and turf uses and determine that the products labeled for these uses are eligible for reregistration provided that (i) current data gaps and data needs are addressed, and (ii) the label changes described in this document are adopted and implemented.

The Agency's findings for the pesticide oryzalin are summarized in the enclosed document, *Overview of Oryzalin Risk Assessment*, dated May 26, 2004, which comprises Section VI of this TRED. Further details on EPA's conclusions about the tolerance reassessment of oryzalin may be found in the enclosed list of technical support documents (Appendix C), which are available in the public docket and on the Internet (<http://www.epa.gov/e-dockets>) for viewing.

II. Tolerance Reassessment

A. FQPA Assessment Supporting Tolerance Reassessment Decision

The Agency has conducted risk assessments for oryzalin to ensure that the oryzalin tolerances meet the new safety standards established by FFDCA, as amended by FQPA. These recent risk assessments for oryzalin include evaluation of potential increased susceptibility to infants and children; dietary, drinking water, and residential exposure of adults and children; and aggregate risk from these various exposure pathways. EPA also considered potential cumulative risks for oryzalin and other substances sharing a common mechanism of toxicity as well as potential endocrine effects associated with oryzalin. Details of the Agency's revised risk assessments may be found in Section VI, *Overview of Oryzalin Risk Assessment*, dated May 26, 2004, and in the technical support documents listed in Appendix C.

EPA has determined that risk from exposure to oryzalin is within its own "risk cup." In other words, EPA is able to conclude today that the tolerances for oryzalin meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to oryzalin "fit" within the individual risk cup for this chemical. The Agency's risk assessment conclusions are summarized below.

Dietary Risks from Food. EPA's Tier I dietary risk assessment shows that dietary risks from oryzalin residues in food are low and not of concern. Both acute and chronic dietary exposure from food constitutes < 1% of the population adjusted dose for oryzalin. The estimated lifetime dietary cancer risk from food is 1.5×10^{-7} , and below EPA's level of concern (1×10^{-6}). Therefore, no mitigation measures are necessary to address dietary risk from food.

Dietary Risks from Drinking Water. Estimated environmental concentrations (EECs) of oryzalin in surface- and groundwater are below the acute, short-term, and chronic drinking water levels of comparison (DWLOCs) and are not of risk concern. The 30-year annual mean EEC for groundwater is below the cancer DWLOC. However, the 30-year annual mean EECs for oryzalin in surface water are within the range of the cancer DWLOC of 3.3 ppb. When 30-year annual mean EECs incorporate the regional percent crop area (PCA) factor, values are 4.15 ppb for Florida citrus, 2.51 ppb for California almonds treated by ground application, and 3.41 ppb for California almonds treated by aerial application. EPA gathered additional information on these scenarios to determine whether refinements could be incorporated so that the EECs better reflect actual use of oryzalin in the field.

Refinement of Drinking Water EECs. Strip Treatment of Orchard Trees. EPA received public comments on the preliminary risk assessment for oryzalin that allowed the Agency to better define the use of oryzalin on orchard tree crops and to refine the risk assessment. Both the California

Pistachio Commission and the Almond Hullers and Processors Association commented that oryzalin is applied only to the tree row, the berm or strip directly under the trees, following the irrigation lines. These organizations state that other methods of weed control are used for the area between tree rows due to the high cost of oryzalin. The California Pistachio Commission claims that with strip treatment, only 33 to 50% of the acreage in an orchard is actually treated with oryzalin. The Agency validated these claims by confirming this information with USDA and cooperative extension service staff, and refined the drinking water EECs to reflect the practice of applying oryzalin only as a strip treatment. EPA also verified that oryzalin is applied to citrus as a strip treatment by contacting the University of Florida. When EPA assumes that 50% of the acreage in an orchard is treated with oryzalin, to reflect strip treatment, 30-year mean EEC values are 1.25 ppb for California almonds and 2.18 ppb for Florida citrus, which are below the cancer DWLOC and not of risk concern. Strip treatment is only done with ground application.

Aerial Application of Oryzalin. The 1994 Oryzalin RED limited aerial application to California. At present, only one product is registered for aerial application: Surflan 75W in water soluble packaging (EPA Reg. No. 062719-00110). According to United Phosphorus, the registrant who owns this product, Surflan 75W is a dormant product that is no longer actively manufactured or distributed. Furthermore, this product is no longer registered in California, and USDA has found no evidence of aerial application. Therefore, EPA believes that the 30-year surface water EEC of 3.41 ppb for California almonds treated by aerial application overestimates risk and does not need to be considered because this application method is not used to apply herbicides to orchards in California. To ensure that oryzalin is not applied by aerial application in the future, the technical registrant has agreed to a label restriction for all products to prohibit aerial application.

Water Monitoring. Available monitoring data for oryzalin in surface- and groundwater show detections significantly lower than the screening-level model estimates, which indicate that the modeled EECs are likely to overestimate risk. The US Geological Survey (USGS) National Water Quality Assessment (NAWQA) data showed a highest time weighted annual mean concentration of oryzalin of 0.71 ppb in an urban watershed and 0.13 ppb in an agricultural watershed. According to the USGS/EPA pilot reservoir program, time-weighted annual mean concentrations of oryzalin range from 0.07 to 0.08 ppb in raw water samples and 0.0489 to 0.0754 ppb in finished water samples.

Residential Risks. Residential risks from the use of oryzalin on lawns and bystander exposure from the use of oryzalin on golf courses are not of concern. Risks for residential handlers and post-application risks for adults exposed to oryzalin residues on treated lawns or golf courses are all below EPA's level of concern. In addition, post-application risks to toddlers are below the level of concern for all scenarios but one, incidental oral ingestion of pesticide granules by a toddler, which results in a Margins of Exposure (MOEs) ranging from 75 to 170. The Agency believes that the estimated risks for this scenario are an overestimate and not of concern for reasons discussed later in this document (section III.B.)

Aggregate Risk. For oryzalin, the Agency assessed acute, chronic, and cancer aggregate risks, which consider only food and drinking water exposure; and short-term aggregate risks, which include combined exposures from food, drinking water, and short-term residential exposures. Acute, short-

term, chronic, and cancer aggregate risks were evaluated by comparing EEC values with DWLOCs, as described previously. EPA also conducted a supplemental aggregate dietary cancer risk assessment for food and water by including the 30-year annual mean EEC of 4.15 ppb for Florida Citrus scenario in the DEEM-FCID software used to model the cancer dietary risk. The resulting aggregate cancer risk estimate for food and drinking water is 8.3×10^{-7} , which is $<1 \times 10^{-6}$, and not of concern to the Agency. When the Agency considers risk assessment refinements and uncertainties and label changes, aggregate risks are not of concern. Therefore, no mitigation is necessary.

B. Cumulative Assessment

FQPA requires EPA to consider “available information” concerning the cumulative effects of residues from each individual pesticide and “other substances that have a common mechanism of toxicity.” The Agency considers other substances because low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect associated with a higher level of exposure from any of these individual substances. Unlike other pesticides for which EPA has considered cumulative risk based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for oryzalin. The Agency has found no information indicating oryzalin shares a common mechanism of toxicity with other substances. Oryzalin does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of the risk assessments, EPA has not assumed that oryzalin has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://epa.gov/pesticides/cumulative/>.

C. Endocrine Disruptor Effects

For oryzalin, the only effects which may indicate potential endocrine disruption were those involving the thyroid gland. EPA has considered the risk of these effects in the oryzalin regulatory decision by selecting endpoints based on thyroid effects in the chronic and cancer risk assessment. Further, the Agency is requiring a confirmatory comparative thyroid toxicity study for oryzalin. Oryzalin may also be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption when the Agency’s Endocrine Disrupter Screening and Testing Advisory Committee develops appropriate screening and/or testing protocols.

D. Tolerance Summary

Tolerances are currently established for residues of oryzalin *per se* (3,5-dinitro-N⁴N⁴-dipropylsulfanilamide) on the raw agricultural commodities listed in the table below. The fourteen (14) existing tolerances for oryzalin have been reassessed. In accordance with current Agency practice, some commodity definitions for the oryzalin tolerances will change. Therefore, the 0.05 ppm tolerance for *small fruit* will be replaced with individual tolerances for *berry, group 13; cranberry; grape; and strawberry*; each at 0.05 ppm. The oryzalin tolerance reassessment and modifications in commodity

definitions are presented in Table 1.

The available residue data indicate that oryzalin residues do not concentrate in processed foods, such as olive oil, fruit pomace, or fruit juice. Therefore, no tolerances are required for processed commodities. No tolerances have been or need to be established for animal commodities. Animal feeding studies show no detectable residues in meat, milk, poultry, and eggs. No maximum residue limits (MRLs) for oryzalin have been established or proposed by Codex, and there are no international compatibility issues with respect to U.S. tolerances.

Table 1. Tolerance Reassessment Summary for Oryzalin.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR §180.304(a) Raw Agricultural Commodities (plants only)			
Almond, hulls	0.05	0.05	
Avocado	0.05	0.05	
Fig	0.05	0.05	
Fruit, citrus	0.05	0.05	<i>Fruit, citrus, group 10</i>
Fruit, pome	0.05	0.05	<i>Fruit, pome, group 11</i>
Fruit, stone	0.05	0.05	<i>Fruit, stone, group 12</i>
Kiwifruit	0.05	0.05	
Nut, tree, group 14	0.05	0.05	
Olive	0.05	0.05	
Pistachio	0.05	0.05	
Pomegranate	0.05	0.05	
Small fruit	0.05	0.05	<i>Berry, group 13</i>
		0.05	<i>Cranberry</i>
		0.05	<i>Grape</i>
		0.05	<i>Strawberry</i>
Tolerances listed under 40 CFR §180.304(b) Regional Registrations			
Guava	0.05	0.05	
Papaya	0.05	0.05	

Residue Analytical Methods. The Food and Drug Administration (FDA) Pesticide Analytical Manual (PAM Vol. II) method for oryzalin is adequate for data collection and enforcement of tolerances in food. PAM Method I has a detection limit of 0.01 ppm for plant commodities. This gas-liquid chromatography (GLC)/electron capture detection (ECD) method involves conversion of oryzalin to its *N,N*-dimethyl derivative with methyl iodide. For animal commodities, Method I may be modified using GLC/ECD or high-performance liquid chromatography (HPLC). This modified method has a detection limit of 0.05 ppm and is adequate for purposes of data collection for residues of oryzalin in animal commodities. Because oryzalin residues are not likely to be present in animal commodities at detectable levels, the Agency does not require an enforcement methodology for oryzalin in animal commodities at this time. Also, the registrant has submitted data which indicate that oryzalin is not recovered through any of the multiresidue protocols listed in PAM, Vol I.

III. Reregistration Eligibility Decision for Products Registered for Turf Use

At the time the Agency completed the Oryzalin RED in 1994, EPA did not have sufficient information to determine the reregistration eligibility of oryzalin products for use on residential lawns and turf, and included the necessary studies information in the generic data call-in (DCI) for the RED. Subsequent data from these confirmatory studies now allow EPA to estimate exposure and risks from the lawn and turf uses of oryzalin. The Agency has determined that the products labeled for use on residential lawns and golf course turf are eligible for reregistration provided that (i) current data gaps and data needs are addressed, and (ii) the label changes described in this document are adopted and implemented.

A. Residential Handlers

The Agency has determined that residential handler risks from mixing, loading, or applying products containing oryzalin are not of risk concern and no mitigation is needed. All estimated dermal MOEs are greater than 300, EPA's level of concern for dermal risk, and all estimated inhalation MOEs are greater than 100, EPA's level of concern for inhalation risk. Further, the estimated lifetime cancer risk for residential handlers is less than one in one million (1×10^{-6}), the Agency's level of concern for cancer risk.

B. Residential Re-entry

Adults. The Agency has determined that re-entry risks for adults walking on treated lawns or playing golf on treated turf are not of concern; all dermal MOEs for adults are $\$1,000$ and not of concern. Lifetime cancer risk estimates from post-application dermal exposure to adults from residential lawns or golf courses range from 1.3×10^{-7} to 3.5×10^{-9} , which are not of concern. Because none of the post-application risk estimates for adults are of concern, no mitigation is needed.

Toddlers. EPA estimated dermal exposure and risk from re-entry to treated lawns as well as incidental oral exposure and risk to toddlers who inadvertently ingest residues of oryzalin. The Agency focused on toddlers because this age group is expected to have the highest potential exposure of all children. Dermal MOEs for toddlers are all \$850 and not of risk concern. MOEs for incidental oral ingestion are \$380 for all scenarios but one, and not of risk concern. However, for the scenario of incidental oral ingestion of pesticide granules, the MOE is 170 for a typical product containing 0.75% active ingredient and 75 for the single product containing 1.67% active ingredient. The Agency believes that the post-application risk to toddlers from ingestion of treated granules from the application area is greatly overestimated and not of risk concern for the following reasons:

- < This scenario assumes that the granular formulation for homeowner use contains granules large enough to be seen, picked up, and ingested by a child on the day of application. Granular products for homeowner use are formulated as small particles that are easily dispersed on a lawn or in a flower bed by a drop spreader. These granules are not likely to be picked up or ingested by a child because the granules are so small that they are difficult to see. Moreover, most product labels require that granular products be watered in with a sprinkler and prohibit re-entry until the watering is complete and the grass is dry. Any labels that do not currently require watering in must be amended to specify that the granular product must be watered in to be activated.
- < Available data for granular products formulated for agricultural use show that granular oryzalin dissipates rapidly in the environment. Although no data are available for homeowner products, rapid dissipation of oryzalin products for lawn and turf is also likely.
- < The Agency believes that toddler ingestion of pesticide granules is only an episodic exposure scenario which occurs infrequently. Furthermore, the underlying assumptions in the risk assessment tend to overestimate exposure and risk.
- < The MOE of 75 is based on the single homeowner product containing 1.67% active ingredient (EPA Reg. No. 34704-823), which is the highest percent active ingredient in any homeowner product. All other oryzalin homeowner products contain 1% active ingredient or less. The MOE is 170 for a product containing 0.75% active ingredient, the typical concentration, and not of concern.

In conclusion, the MOE for incidental oral ingestion of pesticide granules is based on conservative assumptions and a screening-level exposure estimate. The Agency believes that the MOE is an overestimate of risk and not of concern. Therefore, no risk mitigation is needed. However, to ensure label consistency, any labels that do not currently require watering in must be amended to specify that the granular product must be watered in with a sprinkler, other irrigation, or rain.

IV. Labeling Changes

The Agency has identified certain label amendments for oryzalin, which are summarized below. The implementation of these label amendments will ensure consistency among labels and are included as part of this tolerance reassessment. For oryzalin products with turf uses to be eligible for reregistration, labels must be amended in accordance with the specific label language given in Table 2.

Strip treatment. All oryzalin products registered for use on orchard crops (citrus, pome fruit, stone fruit, and tree nuts) must be modified to specify that oryzalin is to be applied as a strip treatment to the area around and between trees, under the tree canopy. Oryzalin may not be applied to drive rows or row middles. This will codify existing practice and is expected to have minimal impact on growers. As previously stated, when the practice of strip treatment is considered in the risk assessment, drinking water risks are not of concern.

Aerial Application. To ensure label consistency, aerial application will be prohibited on all oryzalin product labels. This will only affect the label for Surflan 75W water-soluble packages (WSP) (EPA Reg. No. 062719-00110), the only product currently registered for this application method. Because this product is no longer actively marketed or used, this measure is expected to have minimal impact on growers.

Turf Uses. To clarify label directions for granular products registered for use on turf and residential lawns, labels must specify that the product is to be watered in immediately after application to activate the product. The registrant must specify the amount of either rainfall or irrigation necessary to dissolve the granules.

Table 2. Summary of Label Changes for Oryzalin

Relevant Products	Amended Labeling Language	Placement on Label
All agricultural use products	“For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows.”	Directions for Use
All products	“Aerial application is prohibited.”	General Use Precautions and Restrictions

Relevant Products	Amended Labeling Language	Placement on Label
Granular Products for Use on Turf and Residential Lawns - Commercial Use	<p>“This product must be watered in immediately after application to dissolve the granules.”</p> <p>“A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required after product application.”</p> <p>“Do not enter or allow others (including children and pets) to enter the treated areas (except those involved in the watering) until the watering is complete and the grass is dry.”</p>	General Use Precautions and Restrictions
Granular Products for Use on Residential Lawns - Homeowner Use	<p>“This product must be watered in immediately after application to dissolve the granules.”</p> <p>“A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required after product application.”</p> <p>Do not enter treated area until it has been watered and grass is dry. Do not allow children or pets to enter treated areas until watering is complete and the grass is dry.</p>	General Use Precautions and Restrictions

V. Data Gaps and Confirmatory Data Requirements

The Agency has identified several confirmatory data requirements have been identified for oryzalin. These are listed in Table 3 and will be included in a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(2)(B) data call-in (DCI) to be sent under separate cover. These data are not expected to change the regulatory conclusions for oryzalin described in this document, but must be submitted to support the continuing registration of oryzalin.

Table 3. Confirmatory Generic Data Requirements for Oryzalin

OPPTS Guideline Number	Guideline Name	Compound(s) Which Must be Tested	Comment/Rationale
830.7050	UV Visible Absorption	Technical, All Registrants	New data requirement
870.3465	28-day Rat Inhalation study	Technical, All Registrants	New data requirement
860.1520	Magnitude of the Residue in Processed Food/Feed (Citrus)	End-Use Product	Need to explain shift in retention time on chromatogram peak.
860.1650	Submittal of Analytical Reference Standard	Pure Active Ingredient, All Registrants	As requested by EPA Repository
Non Guideline Study	Comparative Thyroid Assay in Young Rats and Adults	Technical, All Registrants	To better characterize thyroid effects (possible endocrine disruption)

VI. Risk Assessment Overview for Oryzalin

The following document, the May 26, 2004, *Risk Assessment Overview for Oryzalin* summarizes the conclusions of the Agency's revised risk assessment. More detailed information on the data, methodologies, assumption, and uncertainties underlying the revised risk assessment may be found in the technical support documents listed in Appendix C.

Overview of Oryzalin Risk Assessment May 26, 2004

Introduction

This document summarizes the Environmental Protection Agency's (EPA or the Agency) human health risk assessment and conclusions for the herbicide oryzalin as presented fully in the document, "*Oryzalin HED Risk Assessment for Tolerance Reassessment Eligibility Decision (TRED)*" dated May 18, 2004. The purpose of this overview is to assist the reader by identifying the key features and findings of the risk assessments, and to allow the reader to better understand the conclusions reached in the assessments. The Agency developed this overview in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to differing formats.

EPA issued a Reregistration Eligibility Decision (RED) for oryzalin in September, 1994 (EPA 738-R-94-016). In the RED, the Agency determined that all products registered at that time were eligible for reregistration *with the exception* of products labeled for use on residential lawns and turf. EPA did not have adequate information to estimate post-application/re-entry exposure for residential lawn and turf uses; therefore, the Agency could not conduct a risk assessment. As part of the RED, EPA required additional studies so that risks from turf grass use could be evaluated. The Agency now has adequate information to make an eligibility decision for oryzalin products with residential lawn and turf uses. Therefore, the risk assessments summarized in this document will serve as the basis for the *Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Oryzalin*, and allow EPA to make an eligibility decision for oryzalin use on residential lawns and turf. The human health risk assessment for oryzalin and all the supporting technical documents are posted on the Internet (<http://www.epa.gov/edockets>) under docket number OPP-2004-0143.

The estimated risks summarized in this document are those that result only from the use of oryzalin. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of exposure to a pesticide and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the

possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for oryzalin. Oryzalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of the risk assessments, therefore, EPA has not assumed that oryzalin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

Use Profile

Oryzalin (4-(Dipropylamino)-3,5-dinitrobenzenesulfonamide) is a selective, preemergent surface-applied herbicide used for control of annual grasses and small-seeded broadleaf weeds. Oryzalin is a dinitroaniline herbicide that controls weeds by disrupting the growth process during seed germination; it does not control established weeds.

Technical Registrant: United Phosphorus Inc.

Use Sites and Use Related Information:

- An estimated 1.4 to 1.9 million pounds active ingredient of oryzalin are used annually in the US. Of this total, approximately 58% is used on agricultural sites with the remaining 42% used on non-agricultural sites.
- Agricultural uses to control weeds on terrestrial food crops include fruit trees (e.g., apples, pears, plums, and citrus); nut trees (e.g., almonds, walnuts, and pistachios); and many types of small fruits (e.g., grapes, raspberry, blueberry, avocado, fig, and kiwi). Based on available use related information, the Agency estimates that 800,000 to 1.1 million pounds active ingredient are used annually on agricultural crops. Its largest agricultural markets, in terms of pounds utilized, are almonds, grapes, apples and pears. For orchard crops, oryzalin is usually applied to the strips directly around and between trees, under the tree canopy but not to the drive rows or row middles.
- Non-agricultural uses include residential lawns, recreational turf, nurseries and landscape ornamentals, golf courses, Christmas tree plantations, and industrial sites. Based on available use related information, 600,000 to 800,000 pounds oryzalin are used annually on these sites.

Of this, 30-35% is used on landscape ornamentals (includes homeowner uses), 40-45% is used on nurseries, 15-20% is used for lawn care (includes residential homeowner uses), and 2-5% is used on golf courses.

Formulations:

- Formulated as granular, water dispersible granules, emulsifiable concentrate, formulation/intermediate liquid, ready-to-use, aqueous suspension, soluble concentrate, and dusts. Formulations for turf and ornamental application are either granulars, emulsifiable concentrates, or ready-to-use products.

Application Methods and Rates:

- Methods -
 - Ground: Band treatment; chemigation; soil broadcast (belly grinder); backpack, ground-boom, tank-type, hose-end, and hand-held sprayers; and granular push spreaders.
 - Aerial: In California only; agricultural crops only (not residential)
- Rates -
 - Ornamentals: application rates range from 1.5 to 4.0 lbs active ingredient/acre (a.i./acre).
 - Turf grass: application rates range from 1.5 to 2.5 lbs a.i./acre.
 - Non-Cropland and Industrial Sites: application rates range from 2.0 to 6.0 lbs a.i./acre.
 - Fruit and Nut Crops and Vineyards (bearing and non-bearing): application rates range from 2.0 to 6.0 lb a.i./acre
 - Ornamental Bulbs: application rates range from 0.75 to 1.5 lbs a.i./acre
 - Evergreen Tree Plantations: application rates range from 2.0 to 4.0 lbs a.i./acre

Human Health Risk Assessment

Dietary Risk

The acute, chronic and cancer dietary (food) risk assessments were conducted for oryzalin using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3), which incorporates consumption data from USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The acute and chronic dietary (food) risk analyses were conducted using tolerance values and assuming 100% crop treated (Tier 1). The cancer

dietary (food) risk assessment used tolerance values and percent crop treated data when available. Acute dietary analyses were conducted for the population subgroup females 13-49 years old, the only population subgroup of concern given the endpoint selected from the available toxicity studies. Chronic dietary analyses were conducted for the general U.S. population and various population subgroups. The cancer dietary risk assessment was conducted for the general U.S. population.

Estimated dietary (food) risks less than 100% of the Population Adjusted Dose (PAD), either acute (aPAD) or chronic (cPAD), are not of concern to the Agency. The aPAD is the dose at which a person could be exposed at any given day and no adverse health effects would be expected. The cPAD is the dose at which an individual could be exposed over the course of a lifetime and not expect an adverse health effect. For the cancer dietary (food) risk assessment, risks less than one in one million (1×10^{-6}) are not of concern to the Agency.

Acute Dietary Risk from Food

The acute dietary (food) risk assessment was conducted using the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM-FCIDTM), using tolerance values and assuming 100% crop treated. This Tier 1 assessment utilized a highly conservative deterministic methodology.

- The estimated acute dietary risk of oryzalin is below the Agency's level of concern; < 1% of the aPAD was occupied for females 13-49 years old at the 95th percentile (Tier 1 Exposure Analysis), the only subgroup of concern.
- EPA calculated the aPAD and dietary risk levels for oryzalin using the following toxicity data: A No Observed Adverse Effect Level (NOAEL) of 25 mg/kg/day was selected for females 13-49 years old for acute dietary exposure based on decreased live fetuses, increased resorptions, and increased post-implantation loss at the Lowest Observed Adverse Effect Level (LOAEL) of 55 mg/kg/day from a rabbit developmental neurotoxicology study.
- The Uncertainty Factor (UF) is 100 (10X for interspecies extrapolation and 10X for intraspecies variability). The special FQPA Safety Factor (SF) was reduced to 1x because there are low concerns for increased susceptibility of the young and no residual uncertainties for pre and/or post natal toxicity.
- The acute Reference Dose (RfD) is 0.25 mg/kg/day, for females 13-49 years old, and is calculated by dividing the NOAEL (25 mg/kg/day) by the UF (100). No appropriate endpoint for the general population was identified.
- The aPAD is 0.25 mg/kg/day, and is calculated by dividing the acute RfD (0.25 mg/kg/day) by the FQPA SF (1X). Because the FQPA SF is 1X, the aPAD and acute RfD are the same.

Chronic Dietary Risk from Food

The chronic dietary (food) risk assessment was conducted using a highly conservative deterministic methodology, using tolerance values and assuming 100% crop treated (Tier 1).

- The estimated chronic dietary (food) exposure at the 95th percentile (Tier 1) to oryzalin for all population subgroups is less than 1% of the cPAD, and therefore not of concern to the Agency.
- EPA calculated the cPAD and dietary (food) risk levels for oryzalin using the following toxicity data: A NOAEL of 14 mg/kg/day was selected for all populations for chronic dietary exposure based on decreased body weight gain and hematology parameters, and increased microscopic findings in the thyroid at the LOAEL of 43 mg/kg/day from a 2-year rat feeding study.
- The UF is 100 (10X for interspecies extrapolation and 10X for intraspecies variability). The special FQPA SF was reduced to 1x because there are low concerns for increased susceptibility of the young and no residual uncertainties for pre and/or post natal toxicity.
- The chronic RfD is calculated to be 0.14 mg/kg/day by dividing the NOAEL (14 mg/kg/day) by the UF (100).
- The cPAD is 0.14 mg/kg/day, and is calculated by dividing the chronic RfD (0.14 mg/kg/day) by the FQPA SF. Because the FQPA SF is 1X, the cPAD and the chronic RfD are the same.

Cancer Dietary Risk from Food

Oryzalin is classified as “likely to be carcinogenic to humans” based on the Agency’s Draft Guidelines for Carcinogen Risk Assessment (July, 1999). A cancer dietary (food) risk analysis was conducted for oryzalin using the DEEM-FCID, version 1.3. The cancer dietary (food) risk assessment was conducted using tolerance values and percent crop treated data where available and assuming consumption of those foods over a 70 year lifetime. The chronic exposure value is multiplied by a linear low-dose response factor (Q_1^*), based on animal studies, to determine the lifetime cancer risk estimate. Cancer dietary (food) analyses were conducted for the general U.S. population.

- The Q_1^* is $0.0078 \text{ (mg/kg/day)}^{-1}$ based on increases in thyroid follicular cell tumors in both sexes, skin tumors in both sexes, and fibroadenomas in females.
- The estimated dietary (food) cancer risk is 1.5×10^{-7} , and below the Agency’s level of concern (1×10^{-6}).

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available and of sufficient quality, to estimate those risks. This section describes the estimated environmental concentrations (EECs) of oryzalin in water. Risks from exposure to these concentrations are discussed later in the section titled “Aggregate Exposure and Risk.”

Oryzalin is the only residue of concern in water; there are no degradates of concern. The major route of oryzalin disappearance is aqueous photolysis, photodegradation on soil surface, and reduction under anaerobic conditions. Oryzalin appears to degrade slowly under aerobic soil conditions and is stable to hydrolysis.

The Agency calculated screening-level EECs for oryzalin using computer modeling for both surface and ground water sources. These modeled values were refined using regional percent crop area factors and new information about oryzalin use obtained from the phase 3 public comments and from Agency outreach to experts in weed management in orchard crops.

Drinking Water Model Estimates

- Drinking water EECs for surface water were estimated using computer modeling with PRZM/EXAMS software (versions PRZM 3.12 and EXAMS 2.975), using the refinements of the Index Reservoir and Percent Crop Area factor. Drinking water EECs from modeling vary depending on different scenarios for geographic location, crop, and pesticide application rates and methods. Scenarios selected for modeling are ones that would result in the highest EECs from the available combinations of crop, use patterns, and location.
- Drinking water EECs for surface water were calculated using five use scenarios, two non-crop uses (golf courses and Christmas trees), and three crop uses (almonds, citrus, and apples) of oryzalin. The most conservative estimates were obtained from the scenario modeling ground applications of oryzalin to Florida citrus at the maximum labeled rate of 6 lb a.i./acre applied twice annually with an interval of 60 days between applications.
- For the purpose of estimating high-end acute risks, EPA uses the 1 in 10 year annual peak concentration of oryzalin in drinking water from surface water sources. For evaluating high-end chronic (non-cancer) risk concerns, the estimated 1 in 10 year annual mean concentration of oryzalin in drinking water is used. The 30-year annual mean concentration is used to evaluate cancer risk concerns. Table 1 presents the modeled EECs for oryzalin in drinking water from surface water sources.
- The drinking water EEC for groundwater was calculated using the Screening Concentration in

Ground Water (SCI-GROW) model. SCI-GROW provides a screening value to use in determining exposure and the potential risk to human health from pesticide residues in groundwater. Scenarios selected for modeling are, again, ones that would result in the highest EEC from the available combinations of crop, use patterns, and location.

- The same five use scenarios used for modeling surface water were considered for determining the EECs for groundwater. The highest EEC was obtained from the California almond and Florida citrus scenarios. The estimated concentration is considered for both the acute and chronic upper bound value for use in the cancer and noncancer risk assessment. Table 1 presents the modeled EEC for oryzalin in drinking water from groundwater sources.

Table 1. Modeled Estimated Exposure Concentrations (EECs) for Oryzalin in Drinking Water

Drinking Water Scenario	Acute (ppb*) 10 yr Peak	Chronic (ppb) 10 yr Annual Mean	Cancer (ppb) 30 yr Annual Mean
SURFACE WATER			
FL Citrus- Ground Application ¹	90.48	6.14	4.15
FL Citrus - Ground Application, Strip Treatment ²	45.07	3.06	2.18
CA Almond ³ - Ground Application, Strip Treatment	33.07	2.29	1.25
CA Almond - Aerial Application ⁴	56.97	13.20	3.41
GROUNDWATER			
All Crops	0.93	0.93	0.93

¹Florida citrus scenario incorporates regional percent crop area (PCA) factor of 0.34. ²For ground application, EPA assumes that only the area under trees (50% of orchard acreage) is treated with oryzalin, in accordance with the common practice of herbicide strip treatment. ³California almond scenario assumes a regional PCA of 0.56 for almonds. ⁴For aerial application, EPA assumes that the entire orchard floor is treated with oryzalin.

*ppb, parts per billion.

Drinking Water Monitoring Data

Monitoring data for oryzalin residues in groundwater and surface water are available, but were not used quantitatively as part of the human health risk assessment for oryzalin. Data from two water monitoring programs were reviewed for occurrence of oryzalin residues; the U.S. Geological Survey's (USGS) National Water Quality Assessment Program (NAWQA), which samples both surface water and groundwater, and the USGS/EPA Pilot Reservoir Monitoring Study, which samples pesticide residues from raw, untreated water and finished, treated drinking water.

In general, available drinking water monitoring data provide qualitative information indicating that the oryzalin residue levels found are substantially lower than the modeled EECs. Further, the highest concentrations of oryzalin seen in the monitoring data were from urban and suburban runoff rather than from agricultural areas. The NAWQA data showed a maximum oryzalin concentration in surface water of 1.9 ppb for an urban watershed and 1.8 ppb for an agricultural watershed. The highest time weighted annual mean concentration of oryzalin was 0.71 ppb in an urban watershed and 0.13 ppb for an agricultural watershed. For groundwater, the NAWQA data showed a range of concentrations of 0.016 to 0.08 ppb. The mean concentration among detections from groundwater was 0.046 ppb.

The peak oryzalin concentrations among water treatment plants drawing from surface water, as measured in the USGS/EPA pilot reservoir program, ranged from 0.07 to 0.13 ppb in raw water samples. Time weighted annual mean concentrations of oryzalin ranged from 0.07 to 0.08 ppb in raw water samples. Finished water samples had a range of concentrations from 0.0123 to 0.0711 ppb and time weighted annual mean concentrations of 0.0489 to 0.0754 ppb.

Residential Exposure and Risk

A review of residential exposure and risk to oryzalin was conducted because there is potential exposure for residential handlers (mixers, loaders, and applicators) during handling and application of oryzalin and/or to persons entering treated sites after its application. Because oryzalin is classified as “likely to be carcinogenic to humans,” EPA also assessed cancer risks for residential handlers and for individuals with post-application exposures.

Oryzalin residential and non-occupational use sites include lawns and turf (commercial/industrial, recreational, and residential), ornamental bulbs, ornamentals (landscape, field grown, and container grown), paths/patios, golf course turf, and nonbearing fruit and nut trees. Only short-term exposures (< 30 days per year) are assessed for oryzalin because of the sporadic nature of homeowner use. Chemical-specific re-entry exposure data have been submitted and found to be adequate for use in assessing residential post-application exposures. For scenarios for which no chemical-specific data are available (e.g., residential handler), an exposure assessment for each scenario was developed using surrogate data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 and data from the Outdoor Residential Exposure Task Force (ORETF). For a more detailed summary of the data used for the residential exposure assessment, see the supporting technical documents on the EPA website.

To estimate residential risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. The standard UF is 100x (10x to account for interspecies extrapolation and 10x for intraspecies

variation), plus any additional safety factor retained due to concerns unique to the protection of infants and children under FQPA. A MOE less than the target MOE, or level of concern (LOC), is generally a risk concern to the Agency.

Toxicity Summary

- Short-term inhalation and incidental, non-dietary ingestion (oral) risk estimates for oryzalin are combined and based on a NOAEL of 25 mg/kg/day from an oral rabbit developmental study which showed decreased body weight gain and food consumption at 55 mg/kg/day (LOAEL). Due to a lack of inhalation toxicity data, the Agency selected an endpoint from the same oral rabbit developmental study for inhalation risk assessments. An absorption factor of 100% was applied for inhalation exposures. The incidental oral and inhalation exposure routes are combined because of the common toxicity endpoint (effects on body weight and food consumption) via the oral and inhalation (oral equivalent) routes.
- Short-term dermal risk assessments for oryzalin are based on a LOAEL of 1000 mg/kg/day at which increased thyroid weights in males and increased bilirubin in both sexes were observed in a 21-day rabbit dermal toxicity study.
- For oryzalin, the 10x FQPA SF has been reduced to 1X for the reasons explained above in the dietary section. Therefore, the target MOE from incidental oral and inhalation exposures to oryzalin is 100. For dermal exposures to oryzalin the target MOE is 300 because the lowest dose tested in the dermal exposure study was the LOAEL, and a 3X UF was added to account for uncertainties from using a LOAEL in place of a NOAEL.
- The Q_1^* used in the cancer risk assessment is $0.0078 \text{ (mg/kg/day)}^{-1}$.

Exposures and Risks for Residential Handlers

- Oryzalin is applied to residential turf grass before weeds emerge at application rates ranging from 0.75 to 2.5 lb ai/acre. Residential handlers can be exposed to oryzalin by mixing, loading, or applying products containing this active ingredient. As is customary for residential exposures assessments, the Agency assumes that residential handlers wear no personal protective clothing. Therefore, residents are assumed to wear short pants, short-sleeved shirt, but no gloves during pesticide applications. Oryzalin is primarily applied with hand-held equipment for residential uses.
- Residential users of oryzalin may be exposed to oryzalin via dermal and inhalation routes during handling (mixing, loading, and applying) of the pesticide. Dermal exposure cannot be combined with oral and inhalation exposures because different toxicological effects are

associated with these different routes of exposure.

- The Agency estimated residential handler risk for the following five short-term scenarios:
 1. *Mixing, loading, and applying liquid spray formulations by backpack sprayer;*
 2. *Mixing, loading, and applying liquid spray formulations by low-pressure handwand;*
 3. *Mixing, loading, and applying liquid spray formulations by hose-end sprayer;*
 4. *Loading and applying granular formulation with a belly-grinder; and*
 5. *Loading and applying granular formulation with a push-type sprayer.*
- Short-term risk to residential handlers is measured by a Margin of Exposure (MOE). For oryzalin, an MOE of 100 (or greater) from incidental oral and inhalation exposures is not of concern. For dermal exposures, an MOE of 300 or greater is not of concern. Short-term MOEs for residential handlers exposed to oryzalin are summarized in Table 2.
- Cancer risk estimates for residential handlers (mixing and applying) and people entering treated sites after oryzalin applications are based on the following assumptions:
 - < Average body weight is 70 kg, which represents a typical adult.
 - < The number of consecutive years a handler applies the product or post-application exposure could occur is 50 years.
 - < Average handler or post-application exposure occurs on one day per year.
 - < Average lifetime is 70 years.
 - < Dermal absorption factor for oryzalin is 2.3% based on a dermal absorption study in Rhesus monkeys.
- < Estimated cancer risks for residential handlers are summarized in Table 2 below. All estimated cancer risks are $<1 \times 10^{-6}$ (all $<1.0 \times 10^{-8}$), and therefore not of concern to the Agency.

<
Table 2. Summary of Residential Handler Risks for Oryzalin

Application Scenario	Short-Term Margin of Exposure (MOE)		Lifetime Cancer Risk
	Dermal	Inhalation	
Spray formulation, backpack sprayer	9,200	39,000	1.0 X 10 ⁻⁸
Spray formulation, handwand	470	39,000	1.8 X 10 ⁻⁸
Spray formulation, hose-end sprayer	13,000	80,000	5.2 X 10 ⁻⁹
Granular formulation, belly grinder	640	28,000	2.0 X 10 ⁻⁸
Granular formulation, push- type spreader	100,000	2,000,000	2.0 X 10 ⁻¹⁰

Exposures and Risks for Residential Post-application Re-entry

EPA has determined that there are potential exposures following oryzalin applications to lawns or turf due to re-entry activities, such as mowing, watering and other yard work, as well as recreational activities. As previously mentioned, the current label application rates for oryzalin range from 1.5 to 2.5 lb ai/acre. The duration of post-application dermal exposure is expected to be short-term only, based on oryzalin turf residue dissipation data and because oryzalin labels prescribe application no more than 2 times per year. Post-application exposures were estimated using assumptions from the Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Post-application dermal exposure estimates also incorporated data from a chemical-specific turf transferable residue study.

Seven post-application scenarios were assessed for risks associated with spray and granular applications of oryzalin:

1. *Dermal exposure to treated turf grass - adults and children.* This scenario assumes that oryzalin residues are transferred to the skin of adults/toddlers who enter treated yards for recreation, yard work, or other homeowner activities.
2. *Dermal exposure to recreational golfer from playing on treated turf grass (adults).* This scenario assumes that a golfer re-enters the course after oryzalin sprays have dried and then plays a four hour round of golf.
3. *Toddler ingestion of residue from treated turf grass via hand-to-mouth activities.* This scenario assumes that turf is contacted and hands are mouthed by toddlers who play on treated grass.
4. *Toddler ingestion of residue via object-to-mouth activity while on treated turf grass.* This

scenario assumes that pesticide residues are transferred to objects and are subsequently ingested as a result of mouthing the object.

5. *Toddler ingestion of soil from treated area.* This scenario estimates doses among toddlers from incidental ingestion of soil containing pesticide residues.
6. *Aggregate toddler incidental oral ingestion.* This scenario estimates hand- and object-to-mouth, and soil ingestion added together to represent an overall risk from exposure to previously treated turf grass. Granular ingestion is considered to be episodic behavior and is therefore not aggregated (see below).
7. *Toddler ingestion of granules from treated area.* This scenario estimates dose among toddlers from episodic non-dietary ingestion of pesticide granules.

Post-application risks to adults are summarized in Table 3. For all scenarios, estimated dermal risks are greater than 300 (all >1,400 on day 0), and therefore dermal risk is not of concern. Estimated lifetime cancer risk for adults is less than 1×10^{-6} from post-application exposure (all are $<1.3 \times 10^{-7}$), and therefore not of concern to the Agency.

Table 3. Adult Post-Application Risks from Orzyalin

Scenario	Total Transferable Residues (TTR), $\mu\text{g}/\text{cm}^2$	Short-term Dermal MOE	Lifetime Cancer Risk
Adult Bystander Exposure from Treated Lawn	0.07 (granular IN)*	3,3000	5.4×10^{-9}
	0.2 (granular CA)	1,3000	1.4×10^{-8}
	0.3 (spray MS)	7,000	2.6×10^{-8}
	0.7 (spray IN)	3,500	6.0×10^{-8}
	1.7 (spray CA)	1,400	1.3×10^{-7}
Adult Golfer	0.07 (granular IN)*	480,000	7.0×10^{-9}
	0.2 (granular CA)	190,000	9.7×10^{-10}
	0.3 (spray MS)	10,000	1.8×10^{-9}
	0.7 (spray IN)	50,000	3.5×10^{-9}
	1.7 (spray CA)	21,000	8.8×10^{-9}

*Indicates data used to derive TTR - oryzalin turf transferable residue study conducted with a granular formulation at sites in Indiana and California and with spray formulation at sites in Mississippi, Indiana, and California.

Risk estimates for all toddler post-application re-entry scenarios are summarized in Table 4 below. Because toddlers may ingest oryzalin residues on turf from a variety of activities, EPA has

combined risk estimates (MOEs) for incidental oral exposure. The Agency combined risk estimates for incidental oral ingestion from hand-to-mouth activity, object-to-mouth activity, and soil ingestion. However, the scenario of ingestion of pesticide granules was not included in this combined risk estimate because it occurs infrequently.

Table 4. Post-Application Risk to Toddlers from Use of Oryzalin on Lawns

Toddler Exposure Scenario	Margin of Exposure (MOE) on Day of Oryzalin Application	
	Spray Formulation	Granular Formulation
Dermal exposure to treated grass	850-4,200	7,700-20,000
Ingestion from hand-to-mouth activity	500	2100
Ingestion from object-to-mouth activity	2000	2100
Ingestion of soil from treated lawn	140,000	140,000
Combined incidental oral ingestion (total of hand-to-mouth, object-to-mouth, & soil ingestion)	380	1000
Ingestion of granules from treated area	N/A	75 (1.67% ai formulation) 170 (0.75% ai formulation)

Risks from only one scenario are below the Agency’s level of concern: toddler ingestion of granules from treated area (scenario 7). The MOE of 75 is based on the single homeowner product containing 1.67% active ingredient (EPA Reg. No. 34704-823), which is the highest percent active ingredient in any homeowner product. All other oryzalin homeowner products contain 1% active ingredient or less. The MOE is 170 for a typical product containing 0.75% active ingredient, and not of concern. This scenario of toddler exposure from ingested granules is based on conservative assumptions and is believed to overestimate exposure and risk. Further, when oryzalin is watered in after application, as required by most product labels, the granules dissolve and are not available for ingestion by toddlers. Estimated dermal risks are greater than 300 for all post-application re-entry scenarios for adults and toddlers; therefore, dermal risk is not of concern. Risk estimates from incidental oral ingestion by hand-to-mouth activity, object-to-mouth activity, soil, and these three scenarios combined are all greater than 100 and not of concern.

Combined Residential Handler and Post-application Exposure

Exposures from different residential exposure pathways may be added (e.g., when a residential user applies oryzalin and then re-enters the treated area for various activities on the same day). Combined dermal risk estimates for individuals who could experience exposures from both handling (mixing, loading, applying) oryzalin products and re-entry activities (e.g., mowing, watering, other yard work) are all greater than 300 and not of concern. Combined cancer risks for handler and post-

application exposures to oryzalin are also not of concern ($<1.3 \times 10^{-7}$).

Aggregate Exposure and Risk

An aggregate risk assessment evaluates the combined risk from dietary exposure to residues in food and drinking water and, if applicable, residential exposure to homeowners. For aggregate risk, EPA typically considers combined exposures from food and residential sources and calculates a drinking water level of comparison (DWLOC) which represents the maximum allowable exposure through drinking water after considering food and residential exposures. If the estimated environmental concentrations (EECs) in water are less than the DWLOCs, EPA does not have concern for aggregate exposure. If EECs are greater than DWLOCs, EPA will conduct further analysis to characterize the potential for aggregate risk of concern.

- For oryzalin, the aggregate exposure scenarios are acute, short-term, chronic (non-cancer), and cancer. Acute, chronic, and cancer aggregate risks are based on combined food and drinking water exposures only. Short-term aggregate risks estimates include combined exposures from food, drinking water, and short-term residential exposures.
- As indicated in Table 5, the EECs for acute, short-term, and chronic (non-cancer) exposures were less than the corresponding DWLOCs; therefore, estimated aggregate risks for these exposure durations are below EPA's level of concern. The 30-year annual mean EEC for groundwater is below the cancer DWLOC. However, the 30-year annual mean EECs for oryzalin in surface water are below or within the range of the cancer DWLOC of 3.3 ppb, and of possible risk concern.

Table 5. Summary of Estimated Aggregate Risks for Oryzalin

Exposure	Surface Water EEC (ppb)	Groundwater EEC (ppb)	DWLOC (ppb)
Acute	21.41-90.48	0.93	7500
Short-Term	1.93-6.14	0.93	1800
Chronic (Noncancer)	1.93-6.14	0.93	1400
Cancer	1.25-4.15	0.93	3.3

- The EEC value of 4.15 ppb for Florida citrus assumes that the entire orchard floor is treated with oryzalin. However, use of oryzalin on Florida citrus is negligible. Also oryzalin is applied to orchard crops, including citrus, as a strip treatment. In other words, oryzalin is applied only to the area under the tree canopy around trees and between trees in a row. It is not applied to the empty space between rows of trees (drive rows or row middles).
- The Agency adjusted the EECs for Florida citrus and California almonds to reflect the practice of strip treatment. When EPA assumes that 50% of the acreage in an orchard is treated with

oryzalin, to reflect strip treatment, 30-year mean EEC values are 1.25 ppb for California almonds and 2.18 ppb for Florida citrus.

- The EEC value of 3.41 ppb for California almonds (aerial application) marginally exceeds the cancer DWLOC of 3.3 ppb. One oryzalin product, Surflan 75W water-soluble pack (WSP) (EPA Reg. No. 062719-00110), is labeled for aerial application in California, but this product is dormant and is not actively sold or marketed.
- To further evaluate aggregate cancer risk, EPA added the 30-year EEC of 4.15 ppb for cancer directly into the DEEM-FCID software. Based on this analysis, the estimated cancer risk from all sources of dietary exposure to oryzalin (food and water) is 8.3×10^{-7} , which is $<1.0 \times 10^{-6}$, the Agency's level of concern for the U.S. general population.

Occupational and Ecological Risk

For purposes of this risk assessment and tolerance reassessment, no occupational or ecological risk assessment was conducted for oryzalin. Occupational and ecological risk management decisions were made as part of the 1994 Oryzalin RED.

Appendix A
Use Patterns Subject to this Tolerance Reassessment
and Reregistration Eligibility Decision

Table 1. Food Use Patterns Subject to this Tolerance Reassessment Only*

i.	Application Type	Representative Formulation** (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Re-entry Interval (Hours)	Use Limitations
Almond, Citrus Fruit, Pome Fruit, Stone Fruit, Tree Nuts, Avocado, Fig, Filbert, Grape, Kiwi, Olive, Pistachio, Pomegranate, Small Fruit and Berry (Bearing and Non-bearing)							
i.	Broadcast; band treatment; chemigation	75% Water Soluble Powder (62719-106)	5.85	12	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.
ii.	Pre-emergent						
iii.	Ground equipment						
i.	Low Volume Spray, directed spray	75% Water Soluble Powder (62719-110)	3.9	12	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.
ii.	Not specified						
iii.	Ground equipment						
i.	Broadcast ; band treatment	85% Dry Flowable (62719-138) (62719-153)	6.04	11.9	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.
ii.	Pre-emergent						
iii.	Ground equipment						

i. ii. iii.	Application Type Application Timing Application Equipment	Representative Formulation** (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Re-entry Interval (Hours)	Use Limitations
i. ii. iii.	Broadcast; band treatment; chemigation Pre-emergent Ground equipment	41% Flowable Concentrate (72167-17)	6.0	12	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.
i. ii. iii.	Broadcast; band treatment; chemigation Pre-emergent Ground equipment	40.4% Flowable Concentrate (73917-4)	6.0	12	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.
Almond, Citrus Fruit, Pome Fruit, Stone Fruit, Tree Nuts, Avocado, Fig, Filbert, Grape, Kiwi, Olive, Pistachio, Pomegranate, Small Fruit and Berry (Non-bearing)							
i. ii. iii.	Broadcast Pre-emergent Ground equipment	40.4% Flowable Concentrate (62719-113) (72167-15) (73917-3)	4.0	12	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.
i. ii. iii.	Broadcast Pre-emergent Ground equipment	1% Granular (62719-136)	3	18	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.
i. ii. iii.	Broadcast Pre-emergent Ground equipment	60% Dry Flowable (62719-174)	3	12	Not Specified	24	For orchard crops, including citrus, pome fruits, stone fruits, and tree nuts, apply product only as a strip treatment in the tree rows; do not apply to row middles or drive rows Aerial application is prohibited.

* Use information, including restrictions, apply only to this tolerance reassessment decision. Please see the September 1994 Oryzalin RED for additional use restrictions.

**This table provides at least one typical formulation for each use pattern but does not represent all formulations registered for a particular use pattern.

Table 2. Non-food Use Patterns subject to Reregistration Eligibility Decision for Turf

i.	Application Type	Representative Formulation* (EPA Reg. No)	Maximum Single Application Rate, lbs ai/Acre	Maximum Seasonal Rate, lbs ai/A	Re-Entry Interval	Use Limitations
Lawns/Turf (includes golf courses, outdoor recreation areas, industrial parks, shopping centers, etc.)						
i.	Broadcast	11.8% Ready to Use (524-449)	4	12	Not Specified	
ii.	Foliar/When Needed					
iii.	Backpack sprayer					
i.	Broadcast	40.4% Emulsifiable Concentrate (54705-5)	2	8	Not Specified	Aerial application is prohibited.
ii.	When Needed					
iii.	Sprayers, backpack and handheld					
i.	Spray	2.84% Emulsifiable Concentrate (802-564, 802-565)	2	Not Specified	Not Specified	Aerial application is prohibited.
ii.	When Needed					
iii.	Pressure, Tank-type, or Hose-end Sprayers					
i.	Spray	3% Soluble Concentrate (54705-11)	2	Not Specified	Not Specified	Aerial application is prohibited.
ii.	Pre-emergent					
iii.	Hose-end sprayer					
i.	Broadcast	1.67% Granular (34704-823)	2.5	5	Not Specified	Product must be watered in immediately after application to dissolve the granules. A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required.
ii.	When needed					
iii.	Spreader					
i.	Broadcast	1% G (961-352) (8660-150) (62719-158)	2	4	Not Specified	Product must be watered in immediately after application to dissolve the granules. A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required.
ii.	Pre-emergent					
iii.	Spreader					
i.	Broadcast	1% G (7401-415) (62719-261) (8660-150)	1.5	3	Not Specified	Product must be watered in immediately after application to dissolve the granules. A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required.
ii.	Late winter, pre-emergent, when needed					
iii.	Spreader					

i.	Application Type	Representative Formulation* (EPA Reg. No)	Maximum Single Application Rate, lbs ai/Acre	Maximum Seasonal Rate, lbs ai/A	Re-Entry Interval	Use Limitations
Lawns/Turf (includes golf courses, outdoor recreation areas, industrial parks, shopping centers, etc.)						
i.	Broadcast	0.85 or 0.86% Granular (8660-139) (32802-30) (62719-193)	1.5	3	Not Specified	Product must be watered in immediately after application to dissolve the granules. A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required.
ii.	Pre-emergent, Spring					
iii.	Spreader					
i.	Broadcast	0.75% Granular (62719-159)	2	4	Not Specified	Product must be watered in immediately after application to dissolve the granules. A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required.
ii.	Pre-emergent					
iii.	Spreader					
i.	Broadcast	0.5% Granular (35512-29)	2	4	Not Specified	Product must be watered in immediately after application to dissolve the granules. A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required.
ii.	Not specified					
iii.	Spreader					
i.	Broadcast	0.575% Granular (62719-149)	1.5	3	Not Specified	Product must be watered in immediately after application to dissolve the granules. A single rainfall or irrigation of <i>[registrant, please insert]</i> inches or more is required.
ii.	When needed					
iii.	Spreader					

*This table provides at least one typical formulation for each use pattern but does not represent all formulations registered for a particular use pattern.

APPENDIX B

Data Supporting Reregistration of Oryzalin Residential Turf Uses

<i>REQUIREMENT</i>		<i>MRID CITATION(S)</i>	
<i>OCCUPATIONAL/RESIDENTIAL EXPOSURE</i>			
<i>875.2100</i>	<i>132-1A</i>	<i>Foliar Residue Dissipation</i>	<i>45040701</i>
<i>875.2200</i>	<i>132-1B</i>	<i>Soil Residue Dissipation</i>	<i>45040702</i>
<i>875.2400</i>	<i>133-3</i>	<i>Dermal Passive Dosimetry Exposure</i>	<i>44339801</i>
<i>875.2500</i>	<i>133-4</i>	<i>Inhalation Passive Dosimetry Exposure</i>	<i>44339802</i>
<i>None</i>	<i>231</i>	<i>Estimation of Dermal Exposure at Outdoor Sites</i>	<i>44339801</i>
<i>None</i>	<i>232</i>	<i>Estimation of Inhalation Exposure at Outdoor Sites</i>	<i>44339802</i>

Appendix C

Technical Support Documents for the Oryzalin TRED

Bill Chism. *Response to Public Comments on the Preliminary Risk Assessment for Oryzalin*. Docket # OPP-2003-0369. April 22, 2004.

Becky Daiss. *Residential Exposure Assessment for the Tolerance Reassessment Eligibility Decision (TRED) for Oryzalin*. August 19, 2003.

James Hetrick. *Analysis of Oryzalin Monitoring Data from the National Water Quality Assessment Program (NAWQA): Supplemental Information for the Oryzalin Tolerance Reassessment*. July 8, 2003.

James Hetrick. *EFED Refinement and Characterization for the Oryzalin Drinking Water Exposure Assessment for California almonds and Florida Citrus*. May 10, 2004.

Thurston Morton. *Oryzalin HED risk Assessment for Tolerance Reassessment Eligibility Decision (TRED)*. May 18, 2004.

Thurston Morton. *Oryzalin. Revised Cancer Dietary Exposure Assessment for the Tolerance Reassessment Eligibility Decision (TRED)*. May 18, 2004.

USEPA. Office of Pesticide Programs. *Reregistration Eligibility Decision (RED): Oryzalin*. September 1994. (EPA 738-R-94-016)

APPENDIX D

Bibliography of Data Supporting Reregistration of Oryzalin on Residential Turf

MRID

Citation Reference

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- 44339801 Beard, K. (1997) Evaluation of Applicator Exposures to Surflan A.S. During Mixing, Loading, and Application with Backpack Sprayers: (Final Report): Lab Project Number: HEH282: HEH 282: HEH 286. Unpublished study prepared by The Dow Chemical Co. 152 p.
- 44339802 Myers, C.; Murphy, P. (1997) Surflan A.S.: Development and Validation of Monitoring Methods for Assessing Worker Exposures: Lab Project Number: HEH 286. Unpublished study prepared by The Dow Chemical Co. 39 p.
- 45040701 Stafford, L. (2000) Dissipation of Transferable Residues of Isoxaben and Oryzalin on Turf Treated with Formulation of the Pesticide: Lab Project Number: RES97076. Unpublished study prepared by Dow AgroSciences LLC. 142 p.
- 45040702 Selman, F. (2000) Oryzalin: Evaluation of Need for Soil Dislodgeable in Turf: Lab Project Number: GH-C 5051. Unpublished study prepared by Dow AgroSciences LLC. 17 p.